An Adaptation of Interpersonal Psychotherapy for Depression within Primary Care (IPT-Brief):

A randomised trial of IPT-B versus waiting list control in the treatment of Major Depressive Disorder

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DECLARATION

"I certify that this is a true and accurate account of the work carried out. This thesis has been composed by myself and the work herein is my own."

Signed…

Patricia A.M. Graham

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The original 16-session model of Interpersonal Psychotherapy for Depression (IPT: Klerman, Weissman, Rounsaville and Chevron, 1984) was adapted to an abbreviated 8-session version (IPT-B) and initially applied to a single-case pilot study, prior to the present randomised trial. The adaptation was carried out in response to the findings of Shapiro *et al.* (1994) in which mildly to moderately depressed patients showed strong, positive outcomes, regardless of whether they had received 8 or 16 sessions of either cognitive-behavioural or psychodynamic-interpersonal psychotherapy. A total of 49 depressed patients were randomly allocated to one of two groups: (1) IPT-B or (2) waiting list control. Patients in the IPT-B group demonstrated a reduction of severity of depression at a higher rate than would be expected to occur with the passage of time alone. There was no evidence however, of a differential improvement in the perceived quality of interpersonal relationships. Secondary analyses demonstrated that, when stratified for severity, severely depressed patients in the IPT-B group exhibited greater improvement than those who were less severely depressed in the same group. By two-month follow-up, 73% of all IPT-B patients made what was considered to be a **clinically significant** improvement. The effectiveness of IPT-B was witnessed by the NNT result of less than one, for both self-report and clinician-rated clinically significant change. The economic evaluation extended these findings and demonstrated the relative cost effectiveness of IPT-B as compared to an *estimated* standard clinical practice of CBT. Implications of the results are discussed and further research with IPT-B is suggested to determine whether (a) an extended follow up period will demonstrate improvement in the quality of relationships; (b) it will outperform alternative active treatments, such as 16 sessions of standard IPT, CBT and/or pharmacotherapy (c) other patient characteristics will predict reliable change and/or severity of outcome.

CHAPTER 1.0

INTRODUCTION

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1.1 SUMMARY

In 1990, depression was the fourth most important determinant of the global burden of disease and the largest determinant of disability in the world (Murray & Lopez, 1994). According to Andrews (2001) that burden of depression is not being reduced, partly because too many people do not seek treatment and partly because efficacious treatments are not used effectively (Andrews, Sanderson, Slade and Issakidis, 2000). Research conducted to date has demonstrated that Interpersonal Psychotherapy for Depression (IPT, Klerman, Weissman, Rounsaville and Chevron, 1984) is efficacious, both in terms of reducing depressive symptoms and in extending the well interval in patients with recurrent illness (Elkin *et al.,* 1989; Frank *et al.* 1990). Studies that have been conducted to date have all used a standard 16-20 session model for treatment of the acute episode of depression. In an attempt to examine the **effective** use of IPT, as suggested above, the present study sought to extend the findings of Shapiro *et al.* (1994) whereby they established that both mildly and moderately depressed patients had equivalent, strongly positive outcome **regardless of whether they had been allocated 8 or 16 sessions** of either cognitive-behavioural or psychodynamic-interpersonal psychotherapy. The original 16-session model of IPT was adapted, in adherence with the suggestions of Wilfley, Frank, Welch, Spurrell and Rounsaville (1998), to an 8-session model and tested within a single N case study. The positive results of the case study indicated the present larger N study, in order to determine the effectiveness of the abbreviated model, IPT-B, for depression within a Primary Care setting.

1.2 BRIEF OVERVIEW OF THE DEVELOPMENT OF INTERPERSONAL PSYCHOTHERAPY OF DEPRESSION (IPT)

Interpersonal Psychotherapy of Depression was originally developed in a research framework as part of a clinical trial in the treatment of out-patients with depression. The original authors of Interpersonal Psychotherapy of Depression (IPT), Klerman, Weissman, Rounsaville and Chevron, (1984) state that IPT was not intended to be a new psychotherapy, rather a collection of descriptions of the therapeutic concepts and techniques that clinicians stated were most effective in their treatment of Depression. The authors state that their original aim, when describing the concepts and techniques of what was to eventually become IPT, was to ensure that therapists who were involved in delivering treatment during the New Haven-Boston Collaborative Depression Project (1968) did so in a standardised manner. This first efficacy study of IPT (Klerman, DiMascio, Weissman, Prusoff and Paykel, 1974; Weissman, Klerman, Paykel, Prusoff and Hanson, 1974) was designed to examine several treatment strategies for preventing relapse, following recovery from an acute episode of depression, which had been originally treated with amitriptyline.

In 1984, IPT was described and operationally defined in **Interpersonal Psychotherapy of Depression** (Klerman, *et al.* 1984).

"Our intent was not to develop a new psychotherapy, but to describe what we believed was reasonable and current practice with depressed patients and might be considered for inclusion under the rubric of short-term psychotherapy."

Klerman and Weissman (1993a) p4.

Since the original description, IPT has been demonstrated to be efficacious for depression, in terms of reduction in depressive symptomatology and improvement in social functioning, in both acute and continuation/maintenance treatment outcome studies (DiMascio *et al.*, 1979; Elkin *et al.,* 1989; Frank *et al.*, 1990; Klerman *et al.*, 1974: Weissman *et al.* 1974, 1979). Based upon the concept that depression occurs in an **interpersonal context,** IPT has two overarching aims: (1) reduction of the symptoms of depression and (2) improvement of the quality of interpersonal relationships.

The following section is structured as:

1. An overview of the theoretical background of IPT including a description of the origins of the interpersonal approach to psychotherapy in general (Meyer, 1957 and Sullivan,

1953) followed by the application of the interpersonal approach to depression through an examination of Attachment Theory (Bowlby, 1969).

2. Examination of the empirical basis for an interpersonal approach to depression by firstly describing the major research which has demonstrated an **association** between interpersonal difficulties with depression and secondly through an examination of social impairments as a **consequence** of depression.

1.3 THEORETICAL BACKGROUND OF INTERPERSONAL PSYCHOTHERAPY OF DEPRESSION

IPT views depression as occurring in the interpersonal context, therefore the following section describes the origins of such a viewpoint.

1.31 Origins of an Interpersonal Approach to Psychotherapy: Adolf Meyer

The interpersonal approach to psychotherapy was originally founded in the US with Adolf Meyer's *'psychobiological'* approach to psychiatric illness (Meyer, 1957). Meyer (1957) used the term *'psychobiology'* to describe his work and theories, referring to the influence of biological mechanisms upon behaviour. Meyer (1957) strongly influenced by Darwin, perceived mental illness as an attempt by the individual to adapt to the changing environment. Indeed, his concept of psychobiology modified the Darwinian principle of biological adaptation to include the organism's adaptation to the ever-changing psychosocial environment. He placed an emphasis on the patient's current psychosocial and interpersonal experiences, in distinction to the psychoanalytic focus on the past and the intrapsychic (Meyer, 1957). Meyer (1957) was interested in dynamic processes but critical of psychoanalysis for focussing on the unconscious and inference before exploring the facts of what the person's actual life experiences were and what he/she thought about them.

1.32 Harry Stack Sullivan and the Interpersonal Paradigm

Harry Stack Sullivan, one of Adolf Meyer's students, viewed psychiatry as follows:

> *"..the scientific study of people and the processes that go on among them, rather than the exclusive study of the mind, of society or the brain."*
>
> Sullivan (1953) quoted in Klerman *et al.* (1984) p47

Sullivan popularised the term *"interpersonal"* as a balance to the then-dominant intrapsychic approach (Sullivan, 1953). He presented the first major alternative to Freud's drive structural model as he believed that classical Freudian Drive Theory was fundamentally flawed

concerning human motivation, as it under-emphasised the larger social and cultural context in accounting for development and psychopathology.

Sullivan therefore stands as the person who most clearly articulated the interpersonal concept, defining Psychiatry as the field of ***interpersonal relations***. With associates, Fromm-Reichmann (1960) and Cohen *et al.* (1954), Sullivan developed a comprehensive and consistent theory of the connections between psychiatric disorders and interpersonal relations for the developing child in the family and for the adult in the multiple transactions of life. Indeed, the interpersonal school is responsible for the emergence of family therapy.

In the interpersonal approach, the unit of observation and therapeutic intervention is the primary social group, the immediate face-to-face involvement of the patient with one or more significant others. The interpersonal approach is distinguished from social-psychiatric approaches by the different social unit it focuses upon. Social psychiatric approaches focus upon large units of society such as health care institutions, large scale macro social processes such as urbanisation; the influence of social class, racial membership, ethnic background; and historical, political, and economic forces. In contrast, the interpersonal approach is most concerned with the individual's closest relationships, most notably family relationships: in the family of origin and in the family of procreation, love relationships, friendship patterns (particularly in adolescence and young adulthood) work relations and neighbourhood or community relationships (Klerman *et al.* 1984).

The roles of major interest to interpersonal psychotherapy occur within the nuclear family (as parent, child, sibling, spouse), the extended family, the friendship group, the work situation (as supervisor, supervisee or peer) and the neighbourhood or community.

The interpersonal approach views the relationship between social roles and psychopathology as occurring in 2 ways:

1. Conflict in social roles can serve as antecedents for clinical psychopathology
2. One of the consequences of mental illness may be an impairment of the individual's capacity to perform social roles.

Although the interpersonal school was initially based on the work of HS Sullivan, it soon came to include some of the theories of the neo Freudians, Frieda Fromm-Reichmann, Erich Fromm and Karen Horney. Indeed, the work of Frieda Fromm-Reichmann and Mabel Blake

Cohen (Cohen, Baker, Cohen, Fromm-Reichmann and Weigert, 1954) provides additional support for the focus of a psychosocial and interpersonal context associated with the onset of mood episodes in their treatment of manic depressive illness.

Sullivan (1953) was also passionate about the benefit of psychoanalysis for therapists as a tool to help the therapist understand the complexity of interpersonal meaning however, the role of personal analysis is not addressed in IPT. Sullivan (1953) stated that people are motivated by *"needs"* separable into one of two categories: (1) satisfaction and/or (2) security (absence of anxiety), both of which may be met in an interpersonal context.

Sullivan (1953) presented an interesting theory of anxiety in which he claimed that an infant discovers himself or his sense of self in relationship with his object (initially, usually the mother). Some of the earliest interactions with the mother will produce anxiety, others will provide care and comfort. From the earliest interaction, the infant will strive to avoid anxiety and gain security and so will avoid interactions that produce anxiety. Sullivan, who believed that relationship patterns repeat themselves throughout the life course, stated that the self consisted of me-you patterns based on experiences that avoid anxiety and **facilitate** security.

The IPT emphasis on the interpersonal and social factors in the understanding and treatment of depression also draws on the work of many other clinicians, especially Fromm-Reichmann (1960), Cohen *et al.* (1954) and Arieti and Bemporad (1978). Becker (1974) and Chodoff (1970) also emphasised the social roots of depression and the need to attend to the interpersonal aspects of the disorder. Frank (1973) applied an interpersonal conceptualisation to psychotherapy, stressing mastery of current interpersonal situations as an important component for success in outcome.

1.33 The Interpersonal Approach to Depression: Attachment Theory

Attachment Theory, as developed by Bowlby (1969), provides a major theoretical source for understanding depression in an interpersonal context and is central to Interpersonal Psychotherapy for Depression, as it views the need for human relationships, particularly emotional bonds, as a major force on human development.

Bowlby (1982) suggested that there is an instinctive propensity to form strong affectional bonds to preferred others and that an unwilling separation from or loss of those bonds leads to various forms of emotional distress including anxiety, anger, despair, **depression**, and

emotional detachment. Bowlby (1969) also suggested that by ensuring a close proximity to the (mother) primary caregiver these bonds promote no less than survival of the species. Bowlby's (1969) work has been extended by Rutter (1972) to show that the child's relationship with others besides the mother can also create attachment bonds and that disruption of these bonds can contribute to the onset of depression. Bowlby's (1969) early writings were understood to mean that there was a biological need to develop a selective attachment with just one person and that the quality of that relationship differed from all others. According to Rutter (1995) what has become clear over time is that there are very definite hierarchies in selective attachments and that it is usual for children to develop selective attachments with a small number of people who are closely involved in child care.

Bowlby (1977) also suggested that many forms of psychopathology are the result of an inability to form or maintain emotional bonds. On the basis of this argument, he suggested a system of psychotherapy that emphasised the connections between early attachment bonds with parental figures and current relational patterns with significant others and stated that Psychotherapy should help the patient examine current interpersonal relationships and understand how they have developed from experiences with attachment figures in childhood, adolescence, and adulthood.

Bowlby (1988) stated that although the capacity for developmental change diminishes with age, change continues throughout the life cycle so that changes for better or worse are always possible and it is this persisting potential for change that gives opportunities for effective therapy.

Parker (1978) describes effective psychotherapy as similar to optimal parenting. Ideal psychotherapy, according to Parker (1978), should combine caring with non-possessive warmth and should provide, as part of the interpersonal therapeutic relationship, a cognitive explanation of distortions of past relationships. The concept of attachment bonds provides a strong theoretical basis for understanding the interpersonal context of depression and for developing psychotherapeutic strategies to correct the distortions produced by faulty attachments in childhood (Bowlby, 1977). As Rutter (1995) suggests though, we are still far from an understanding of the development of relationships and of the ways in which distortions in relationships play a role in psychopathology. Attachment theory has been hugely helpful in bringing about progress in both areas however, it must be recognised that attachment is not the whole of relationships.

1.4 EMPIRICAL BASIS FOR AN INTERPERSONAL APPROACH TO DEPRESSION

Empirical research has demonstrated an association between interpersonal difficulties in the current social environment with clinical depression (Brown and Harris, 1989; Henderson, Byrne and Duncan-Jones, 1981). Indeed, a number of psychosocial variables have been demonstrated as being associated with the onset and course of depression, for example, inadequate social attachments, lack of social support and stressful life events and ongoing difficulties (Brown and Harris, 1989).

Several longitudinal studies have focused on the psychosocial and interpersonal *consequences* of depression demonstrating that various social impairments are a consequence of depression and also that impairments in social functioning often persist long after the symptoms have decreased.

1.41 Inadequate Social Attachments, Lack of Social Support and Depression

Brown and Harris (1978) first reported that a significant proportion of depressed females from a community survey of women living in London, had experienced a provoking agent (i.e. a severe event and/or major ongoing difficulties) of etiological importance. Furthermore, they defined "vulnerability factors" of depression, such as the lack of a confiding or intimate relationship and the presence of several young children in the home. These vulnerability factors were perceived to contribute to depression only in the presence of a provoking agent. Brown and Harris (1978) suggested that the vulnerability factors were not capable of producing depression in their own right but increased the risk in the presence of a provoking agent. In a further London study in Islington (Brown, Andrews, Harris, Adler & Bridge, 1986), low self esteem and poor social support acted as vulnerability factors.

The importance of the presence of a buffer against depression originated from the work of Brown and Harris (1978). Indeed, these studies suggested that social support is a powerful moderating variable in the prevention of depression. Individuals may be protected from adverse consequences through the stress-buffering effects provided by supportive relationships. Intimacy has been proposed as an important component of care-eliciting and supportive interpersonal relations (Brown and Harris, 1978). Research on this aspect of attachment bonding in relationship to the development of depression was reported by Brown, Harris, and Copeland (1977) who stated that the presence of an intimate and confiding relationship with a man, usually the spouse, was a strong protection against the development

of a depression in the face of life stress. The crucial aspect of social bonds seems to be, not their availability, but how adequate they are perceived to be when one is under stress.

Henderson (1979) confirmed the clinical association between weak social bonds and depression, recognising that "close personal relations" provide opportunities for intimacy, nurturance, validation of self-worth and a sense of connectedness with others. Henderson, Byrne and Duncan-Jones (1981) discussed the relevance of the perceived adequacy (versus availability) of social bonds in terms of the power to reduce the risk of depression, especially when someone is facing a distressing situation. The conclusion in the longitudinal study was as follows:

> *"The actual availability of social relationships probably has little to do with the causes of neurosis. The perceived adequacy with which others meet the individual's requirements, especially under adversity, seems much more important."*
>
> Henderson *et al.* (1981) p197

Interestingly, the authors of IPT have suggested that the symptoms of depression may be viewed as being care-eliciting behaviour which may indeed be adaptive as:

> *"...they emerge when persons consider themselves deficient in care, concern and interest from others. These studies suggest that adequate social relationships may indeed play an important role in recovery from and in the prophylaxis of depressive episodes, particularly in the presence of adversity."*
>
> Klerman *et al.* (1984) p59

Brugha (1995) has reviewed theoretical and research aspects of social support and psychiatric disorder, and also the history of social support, stating that it began to influence studies of clinical disorders in the 1970s. Brugha (1995) argues that it is likely that good social support acts as a buffer against the effects of life events **and** has an independent protective effect.

1.42 Stressful Life Events and Depression

A major influence on the work of life events lay in the views of Adolph Meyer (1957) who introduced the life chart as a way of charting life history, psychiatric and physical illnesses and stressful circumstances, and he emphasised that various life events within common experience could be an important part of the aetiology of a disorder (Meyer, 1951). There are challenges which face studies of life events such as: (1) obtaining reliable and valid information; (2) elimination of events that are consequences of illness; (3) quantification of

stress. However, since the early work, a number of interviews have been used in life events research which take account of these challenges e.g. The Bedford College Interview (Brown and Harris, 1978), the Interview for Recent Life Events (Paykel, 1997) and the PERI (Psychiatric Epidemiology Research Interview) Life Events Scale (Dohrenend, Krasnoff, Askenasy and Dohrenwend, 1978). The first studies involved comprehensive interviews for events and making comparisons with control samples from the general population. Indeed, Paykel *et al.* (1969) found that in the 6 months following a stressful life event, there was a 6 fold increase in the risk of developing depression and that exits of persons from the social network occurred more frequently in the 6 month period prior to the onset of depression.

Brown and Harris (1989) stated that the majority of stressors, preceding depression, involved a degree of loss and disappointment. They described loss as involving a broad range of experiences:

> *"...from literal departures of persons ... to losses of cherished ideas about oneself, one's roles, or other people's relationships with one."*
>
> Brown and Harris (1989) p449

Brown, Harris and Hepworth (1994) have extended this work and state that the common denominator of the depressogenic life stress involves not only loss but also humiliation (e.g. loss of status) and/or entrapment (e.g. caught up in a poor marriage or job).

In terms of depression, issues have been bound up with older debates about classification and endogenous versus reactive depression. In general, the separation of the two groups has not survived well (Paykel, Rao & Taylor, 1984). Depressions vary in the extent to which they are preceded by life stress, but this does not relate well to symptoms pattern. It may be that a group of recurrent severe depressives have less stress (Brown *et al.* 1994; Frank, Anderson, Reynolds, Rietnour & Kupfer, 1994). There have also been studies of the impact of events on depressive outcome. The more recent studies of Brown and co-workers indicate that positive classes of events, such as those which neutralise previous events and 'fresh start' events improve outcome, in those in the milder range of depression (Brown *et al.* 1994; Brown and Moran, 1994). Stressful events appear to lessen the likelihood of improvement and increase relapse, but not in severe recurrent samples (Paykel, Cooper, Ramana and Hayhurst, 1996). 'Fresh start' events have been reported to demonstrate similar effects in a new sample from a trial of befriending, with new severe stressors having an adverse effect (Harris, Brown & Robinson, 1999).

Perhaps one of the most exciting developments in the field of life events is the growing research into the examination of genetic elements in the generation of events (Paykel, 2001).

"Once specific genes contributing to psychiatric disorders have been identified by molecular genetic methods, they provide vulnerability factors to test against effects of life events and event genesis... this is likely to take many years yet."

Paykel, (2001) p 147

Zlotnick, Shea, Pilonis, Elkin and Ryan (1996) reported that despite differential prevalence rates of major depression for men and women, their findings did not support a different process in outcome of illness for men and women; life events and social support were related to severity of depressive symptoms of both genders.

1.43 Marriage - Adult Need for Human Attachment?

There is controversy about whether chronic marital difficulties are antecedents or consequences of depressive episodes (Briscoe and Smith, 1973). Despite this controversy, numerous studies have shown that chronic marital dissatisfaction and discord are significantly associated with clinical depression and that chronic marital turmoil is just as likely to precipitate a depressive episode as is the complete dissolution of the marriage (Pearlin and Lieberman, 1979). Those who are divorced have significantly higher levels of depression than either the continuously married or the never married (Blazer *et al,* 1994; Smith and Weissman, 1992).

"...the actual or threatened disruption of the marital attachment through disputes, separation, or divorce is one of the most common and serious disruptions of attachment in adulthood and is often related to the occurrence of depression ."

Klerman *et al.* (1984) p60

According to Hinchliffe, Hooper and Roberts (1978) marriage serves as the society's response to the individual adult's need for human attachment, as discussed earlier. Ideally, the social and legal contract provides a secure economic and social base for rearing children and creates an opportunity for each partner's needs for mutual care, concern, and affection to be expressed within the stability and security of a committed relationship (Hinchliffe, Hooper and Roberts, 1978). Therefore, the actual or threatened disruption of the marital attachment through disputes, separation or divorce is one of the most common and serious disruptions of attachment in adulthood and therefore is often related to the onset of depression (Klerman *et al*, 1984). Not only does the marital relationship have a high

correlation with and etiological implications for the onset of depression, its effects on patients' responsiveness to treatment and the maintenance of treatment gains have also been demonstrated (Rounsaville, Weissman, Prusoff and Hercet-Barob, 1979; Rounsaville, Prusoff and Weissman, 1980).

1.44 Interpersonal Difficulties as a Consequence of Depression

Consideration for the *impact* of depression on the individual's interpersonal relations and the consequences of the depression for the patient's marriage, family, work and community activities must also be given. There has been a substantial body of evidence which has documented the adverse side effects of depression on the individual's social environment (Wells *et al.* 1989).

There is strong support for the use of an interpersonal approach to the understanding and treatment of depression (Frank and Spanier, 1995). It is widely accepted that antecedent life events and long-term stressors, particularly those involving loss, disappointment, humiliation, and/or entrapment, are important in the onset and course of depression (Frank and Spanier, 1995). Studies cited above, also demonstrate that close personal relations and satisfactory social supports are important in the prevention of depression and that disruption of these attachments plays a significant role in the development of depression. Also, it would appear that persistent deficits in social adjustment are a serious consequence of depressive episodes, as they seem to increase the patient's vulnerability to a recurrence of depression by the likelihood of leading to loss-related life events and ongoing adversities (e.g. chronic marital dissatisfaction, loss of social supports including both personal relationships and general supports).

Given the above overview, IPT focuses on the improvement in the quality of the patient's current social network and mastery of social roles, thereby fostering a facilitation of recovery and reduction in the potential vulnerability to a recurrence of depressive symptomatology.

IPT is therefore interested in the patient's social relationships in all key areas or domains that are important to providing a sense of self-worth. In order to achieve this, there is an awareness of all social influences and life stressors. IPT emphasises all the social concepts while remaining focused on the role of the interpersonal relationships as a vehicle to promote satisfaction and improve the quality of relationships. In turn, IPT aims to reduce the symptoms of depression and other forms of disorder.

1.5 DESCRIPTION OF IPT

The following section is a detailed description of IPT, as outlined by Klerman *et al.* (1984) including: the three phases; four problem areas; goals and strategies; techniques, therapeutic stance; overall characteristics of IPT as compared with CBT and an examination of the major differences between IPT, CBT and Psychodynamic psychotherapy.

Although IPT is one of the most well-studied brief therapies, many clinicians, it is argued (Ablon & Jones, 1999) seem to have difficulty when asked to describe what such a treatment entails. A review of the literature reveals what in theory should occur in IPT. Based on the interpersonal theories of Meyer (1957), Sullivan (1953), and others, IPT is focused on the relationship between mood and interpersonal events. The rationale avoids suggesting whether untoward psychosocial events cause depression or vice versa; indeed for clinical purposes, the authors state that causality may not matter.

As discussed above, IPT is informed by Bowlby's attachment theory (1982) and recognises the profound impact of early developmental experiences and unconscious mental processes (i.e. intrapsychic wishes and conflicts) on later patterns of interpersonal relationships. The clinician focuses on the current social roles and interpersonal relations (Klerman *et al.* 1984). The salient therapeutic points are that patients learn to link their current mood with current interpersonal contacts and to recognise that by appropriately addressing interpersonal situations, they may simultaneously improve both their relationships and their depressed state (Klerman *et al.* 1984).

The focus on 'current relational dilemmas' is based on the assumption that early childhood experiences will be reflected in current patterns of interpersonal relating and in the patient's current social roles.

The interpersonal approach was originally applied specifically to the understanding of **clinical depression**, which is considered to have three component processes (Klerman *et al.* 1984):

1. symptom function
2. social and interpersonal relations
3. personality and character problems

IPT intervenes in the first two levels of these three processes and facilitates recovery of the acute depression by relieving the depressive symptoms and helping the patient develop more effective strategies for dealing with current interpersonal problems associated with the onset of symptoms.

Whilst IPT recognises the role of genetic, biochemical, developmental and personality factors in the causation of and vulnerability to depression, it is interesting to note that **personality is not a focus.** An exception to this general approach is that of IPT for Borderline Personality Disorder (Angus and Gillies 1994) but even here, the Personality Disorder is not confronted directly. Although personality is not a focus, it is believed to affect several aspects of treatment such as predicting psychotherapeutic outcome, altering the patient-therapist relationship and may also be a determinant of the patient's recurrent interpersonal problems.

In IPT, clinical depression is viewed as occurring within an interpersonal context and according to Klerman *et al,* (1984) psychotherapeutic interventions directed at the **interpersonal context** will facilitate the patients' recovery from the acute episode and possibly have preventative effects against relapse and recurrence. IPT has been conceptualised at three levels: (1) strategies; (2) techniques; (3) therapeutic stance. The strategies and goals of IPT, as described in Table 2.0 occur in three phases of treatment: initial, intermediate and final phase.

1.51 Initial Phase of IPT Treatment

The initial phase includes the psychiatric history, diagnostic evaluation and delivery according to standard criteria (e.g. DSM-IV criteria. APA, 1994., Appendix 1.0) and sets the framework for treatment. The patient is also given the "sick role" (Parsons, 1951) which may excuse him/her from overwhelming social obligations, but at the same time makes an explicit requirement for the patient to work in treatment to recover full function. Far from being a negative role assigned to the patient, society it seems, is willing to legitimise sickness as long as the patient follows culturally determined conventions of being ill, such as trying to regain health as quickly as possible, or accepting medical help in overcoming the illness (Christopoulos, 2001). Perhaps one of the major criticisms of the sick role is that as cultural paradigms and norms of illness shift over time, the socially defined parameters of what it means to be sick change, and therefore the sick role will also change within IPT. The

question which then arises, is how contemporary research will be compared with research carried out in future generations, if the sick role will ultimately evolve.

A further criticism of the sick role focuses on the self-evident conclusion that the sick role and subsequent behaviour (of the patient) is an *'eye-of-the-beholder phenomenon'* (Blackwell, 1992) and that too often the eye is that of the physician and in the current case, the eye of the IPT therapist. However, it is argued here that the assignment of the sick role with the diagnosis of depression serve to *'normalise'* the patient's experience and demonstrate that the therapist and patient are talking about the same illness. It also demonstrates the possibilities for recovery and allows the therapist to hold the positive stance, as advocated by the IPT model (Klerman *et al.*1984). The assignment of the sick role is illustrated through an in-depth analysis of a single case presentation (Appendix 2.0) and is argued that it allowed IPT-B to be what was considered to be a 'successful' treatment. A second, 'unsuccessful' case is also presented, interestingly with a lady who was unable to relinquish her adopted sick role, which had proved to be an adaptive role since early childhood but was one which was beginning to *"strain the social contract"* (Christopoulos, 2001 p93).

Those who argue against the sick role may do so from the perspective that assignment of such will eventually *"lead to a shift in preference away from participation"* (Salole, 1997 p1349). However, some would argue that people do not consciously choose to play the sick role once they become a patient. Indeed, Stiggelbout and Kiebert (1997) argue that being a patient is enough to make some behave in a less active way than they might have foreseen for themselves when healthy. These authors argue that the sick role is adopted subconsciously and therefore would be adopted, regardless of the model of therapy being employed. However, implicit in the assignment of the sick role within IPT, is the assumption that ultimately, the patient will take responsibility and the therapist will begin to minimise the sick role, whilst encouraging active participation and eventually independent competence.

A key feature of this time-limited, manualised, antidepressant treatment is that it approaches depression as a clinical disorder. According to Klerman *et al.* (1984) this legitimises the patient's assumption of the sick role, therefore allows the patient to accept help to overcome the illness (Christopoulos, 2001); this places IPT within the broad definition of the medical model. This is perceived as a positive although rather contentious stance, especially amongst

non-medical IPT practitioners. Despite the controversy that surrounds the application of the medical model, it is argued here that **because** of the medical model stance ***and*** the assignment of the sick role, the patient is able to legitimise their illness and, by definition, try to regain their health as quickly as possible (Christopoulos, 2001).

The psychiatric history includes the **interpersonal inventory**, a unique element to IPT, which involves a review of the patient's current social functioning and close relationships. The inventory provides a rich picture of the interpersonal world of the patient, including the relationship patterns, mutual expectations and reciprocal nature of each relationship. The review provides a social framework for understanding the social and interpersonal context of the onset and maintenance of the depressive symptoms and defines the focus of the treatment and interestingly, answers the recent call for routine assessment of patients' support networks (Harris, 2001).

During this phase, the patient is educated with regards to depression through an explicit discussion of the diagnosis and expectations of treatment from the patient's perspective. The therapist offers an interpersonal formulation, which links the depressive symptoms to the patient's interpersonal situation within the framework of one of the four focal areas commonly associated with depression: (1) grief; (2) interpersonal role disputes; (3) role transitions; (4) interpersonal deficits, as described in Table 1.0 below. The major goals of IPT are achieved by ascertaining with the patient which of the four types of problems described was associated with the onset of the presenting episode of depression and by working collaboratively with the patient to renegotiate interpersonal difficulties associated with the primary problem area.

PROBLEM AREA	DESCRIPTION
Grief	Grief is defined as complicated bereavement following the death of a loved one. The therapist's major role is one of facilitation of the mourning process and helping the patient to find new activities and relationships to compensate for the loss.
Interpersonal Role Disputes	Role Disputes are defined as a conflict with a significant other: a spouse, co-worker, close friend, other family member etc. The therapist helps the patient to explore the relationship, nature of the dispute and the options to resolve it.
Role Transition	This focal area includes any change in life status, for example, a job promotion, graduation, beginning or ending of a relationship. The patient is encouraged to deal with the change by recognising positive and negative aspects of the new role they are assuming and negative aspects of the old role that they are replacing.
Interpersonal Deficits	This problem area defines the patient as significantly lacking in social skills, resulting in problems in initiating or sustaining relationships.

Table 1.0 The Four Identified Problem Areas as described by Klerman *et al.* (1984)

1.52 Intermediate Phase of IPT Treatment

Once the major problem area has been identified, a treatment contract is defined and the intermediate phase begins which utilises strategies and goals for each problem area, as defined by Klerman *et al.* (1984) and described in Table 2.0.

FOCUS AREA	STRATEGIES As outlined by Klerman et al. (1984)	GOALS
Grief	1. Review depressive symptoms. 2. Relate depressive symptoms to death of significant other. 3. Reconstruct the patient's relationship with the deceased. 4. Describe the sequence and consequences of events just prior to, during, and after the death. 5. Explore associated feelings (negative as well as positive). 6. Consider possible ways of becoming involved with others.	1. Facilitate the mourning process. 2. Help the patient re-establish interest and relationships to substitute for what has been lost
Role Transitions	1. Review depressive symptoms 2. Relate depressive symptoms to difficulty in coping with recent life change 3. Review positive and negative aspects of old and new roles 4. Explore feeling about what is lost 5. Explore feelings about the change itself 6. Explore opportunities in new role 7. Realistically evaluate what is lost Encourage appropriate release of affect 8. Encourage development of social support system and of new skills called for in new role.	1. Mourning and acceptance of the loss of the old role. 2. Help the patient to regard the new role as more positive. 3. Restore self-esteem by developing a sense of mastery regarding demands of the new roles.
Interpersonal Dispute	1. Review depressive symptoms. 2. Relate depressive symptoms' onset to overt or covert dispute with significant other and with whom patient is currently involved. 3. Determine stage of dispute: Renegotiation, Impasse or Dissolution 4. Understand how nonreciprocal role expectations relate to dispute: 5. Are there parallels in other relationships? 6. How is the dispute perpetuated?	1. Identify dispute. 2. Choose plan of action. 3. Modify expectations or faulty communication to bring about a satisfactory resolution.
Interpersonal Deficits	1. Review depressive symptoms 2. Relate depressive symptoms to problems of social isolation or unfulfillment 3. Review past significant relationships including their negative and positive aspects. 4. Explore repetitive patterns in relationships 5. Discuss patient's positive and negative feelings about therapist and seek parallels in other relationships.	1. Reduce the patient's social isolation. 2. Encourage formation of new relationships

Table 2.0 Strategies and Goals of IPT Treatment as described by Klerman *et al.* (1984)

1.53 Final Phase of IPT Treatment

During the final phase of treatment, the patient in IPT is encouraged to recognise and consolidate therapeutic gains, recognise their independent competence and develop methods of identifying and countering depressive symptoms, should they recur in the future. As in other time-limited therapies, there is an explicit discussion of termination with an acknowledgement that it is potentially a time of grieving, as the patient prepares to terminate the relationship with the therapist.

Perhaps one of the unique characteristics of IPT is in terms of its explicit discussion of termination at the start of therapy. Indeed, from the first session, there is an explicit count down to the end, with the final sessions being described, not only as a time for potential grieving, but also as a useful tool to model a 'successful' ending of a relationship.

As an acute treatment, IPT consists of 16 sessions of once-a-week outpatient treatment; as a monthly maintenance treatment, it may continue for years.

1.54 Techniques of IPT

The IPT manual specifies techniques which incorporate psychodynamically orientated therapies (e.g. exploration, clarification of affect) and cognitive behavioural therapies (e.g. behaviour change techniques, testing perceptions and performance through interpersonal contact). Other techniques specified by the authors include reassurance, clarification, improving communication and decision analysis. As such, IPT is not necessarily considered to be unique in terms of the techniques that it employs although the strategies *are* considered to be distinctive (Klerman *et al.* 1984). The manual distinguishes IPT from alternative psychotherapeutic treatments and explicitly targets the patient's Axis I disorder as opposed to attempting character change.

1.55 Therapeutic Stance in IPT as Compared to CBT

The role of the therapist in IPT is one of active patient advocate and not neutral commentator as in psychoanalysis and one in which a hopeful, supportive, active stance is taken. As transference is not facilitated, the therapeutic relationship is conceptualised to be based in reality, as are the patient's perceptions of interpersonal problems outside of therapy. Perhaps the major distinction between IPT and cognitive behavioural therapy (CBT: Beck, Rush, Shaw, and Emery, 1979) lies within this concept, whereby the cognitive behavioural therapist may consider the patient's perception of interpersonal problems to be biased by

cognitive distortions rather than based in reality. The unit of observation and the target of intervention in IPT is face-to-face interaction with significant others.

Many of the procedures and techniques of IPT therefore share those of other psychotherapies. Important common elements include attempts to help the patient gain a sense of mastery, combat social isolation, restore a sense of social belonging and find meaning in their lives. Table 3.0 summarises the overall characteristics of IPT and the more common specific and non-specific factors between IPT and CBT, which was chosen as the main comparator as:

"Depression may be treated effectively with cognitive therapy or interpersonal therapy. CBT and IPT effectively reduce symptoms of depression."

Treatment Choice in Psychological Therapies and Counselling, (Dept. of Health, 2001 p3-4)

Overall characteristics of IPT	Common non-specific factors of IPT and CBT	More specific factors between IPT and CBT
Time limited, not long term	Helping the patient to feel understood	Time-limited
Focused not open ended	Framework for understanding	Manualised
Current not past interpersonal relationships	Providing hope and optimism	Here and now focus
Interpersonal not intrapsychic	Psychoeducation	Structured (although CBT is considered to be more structured than IPT through the use of agenda setting in CBT)
Interpersonal not cognitive behavioural	Techniques of improvement ▪ *Mobilisation of patient to increased activity* ▪ *Link of mood to activity and reaction to events* ▪ *Testing alternative solutions* ▪ *Examination of expectations vs assumptions about others* ▪ *Role play*	Active
Personality recognised but not the focus		Both IPT and CBT can be combined with antidepressant medication
		Goals of self-assertion and mastery are similar
		The ultimate goals of new skills for prophylaxis are the same

Table 3.0: Overall Characteristics of IPT and the more Common Specific and Non-specific Factors between IPT and CBT.

1.56 Major Differences between IPT and CBT

A major difference amongst the many schools of psychotherapy is in their conceptualisation of the causes of the patient's problems as lying in the remote past, the immediate past or in the present. IPT also differs from other approaches in the particular techniques it uses and in

its overall strategies (Table 2.0). Table 4.0 outlines the major differences between IPT and CBT in the treatment of depression.

IPT	CBT
IPT is informed by Bowlby's attachment theory (1982) and recognises the profound impact of early developmental experiences and unconscious mental processes (i.e. intrapsychic wishes and conflicts) on later patterns of interpersonal relationships.	CBT is based on an underlying theoretical rationale that an individual's affect and behaviour are largely determined by the way in which he structures the world (Beck, 1976). Cognitions are based on assumptions developed from previous experiences.
The patient's perception of interpersonal problems is viewed as being based in reality.	The patient's perception of interpersonal problems is viewed as biased by cognitive distortions rather than based in reality.
Focus on affect	Focus on "hot" cognitions (thoughts with strong associated affects)
No attempt to uncover distorted thoughts systematically.	Attempt to systematically uncover distorted thoughts (negative automatic thoughts, conditional and unconditional beliefs) through the use of techniques such as Socratic questioning.
No homework (although this does appear in adaptations i.e. IPC and IPT-B - described in greater detail).	Homework assignments (*"a significant vehicle from which data which disconfirm many negative thoughts and beliefs can be obtained. ..shift the focus of therapy from subjective, abstract conceptualisations to more objective, realistic, and detailed accounts."* Beck *et al.* (1979) p272.
No attempt to help the patient to develop alternative thought patterns through prescribed practice. Therapist calls attention to distorted thinking in relation to significant others	Attempts are made to help the patient to develop alternative thought patterns through prescribed practice.
Goal is to change the relationship patterns rather than associated depressive cognitions (recognised as depressive symptoms) and thereby alter affect.	Goal is to alter the depressive cognitions and behaviour and thereby alter affect.

Table 4.0: Major Differences between IPT and CBT

1.57 IPT and Psychodynamic Psychotherapy

Although the essential features of a psychodynamic and IPT approach differ i.e. the focus on unconscious mental processes versus the focus on social roles and interpersonal interactions, IPT not only shares some techniques (as described earlier) but also some aspects of dynamic psychotherapy (Hughes, 1999). Both approaches are concerned with the whole life span, and both consider early experience and persistent personality patterns to be of importance. In understanding human transactions, however, the IPT therapist focuses on interpersonal relations whereas the psychodynamic therapist is concerned with object relations. The IPT therapist helps the patient see how their present way of relating to other people and expectations of relationships may have contributed to their depression. Although IPT recognises the patient's past as being of significance, it does not explore the past. The IPT therapist is active both in identifying problem areas and working with the patient in finding alternative strategies to deal with depression in the future.

1.6 OUTCOME RESEARCH: A Brief Review of the Literature

The following section is a review of the outcome research to date, including the efficacy of IPT as an acute treatment for depression in which the original analysis and subsequent reanalyses of the NIMH TDCRP (Elkin *et al.*1989) data are described in detail. Research has demonstrated that IPT is efficacious, both in terms of reducing depressive symptoms and in extending the well interval in patients with recurrent illness (Elkin *et al.* 1989; Frank *et al.* 1990).

1.61 Efficacy of IPT as an Acute Treatment for Depression

The first test of efficacy of IPT as an acute antidepressant treatment was a four-cell, sixteen week randomised trial of IPT, amitriptyline (AMI), their combination and a non-scheduled control group treatment for eighty-one out-patients with Major Depression (DiMascio *et al.*, 1979; Weissman *et al.* 1979). The non-scheduled treatment assigned patients a psychiatrist who could be contacted if required but there were no regular treatment sessions scheduled. There were no significant differences between IPT and medication in terms of a reduction of symptoms at the end of treatment, both treatments were more effective than the control treatment and combined treatment was more effective than either treatment alone (DiMascio *et al.*, 1979; Weissman *et al.* 1979). In a one-year naturalistic follow-up study (Weissman, Klerman, Prusoff, Sholomskas and Padin, 1981) it was found that patients who had received IPT, either alone or in combination, developed significantly better psychosocial functioning by the time of the 1-year follow-up than the medication or treatment control patients. This effect on social functioning was not found for AMI alone and had not been evident for IPT at the end of the 16-week trial (Weissman *et al.* 1981). Many patients across treatments reported requiring additional treatment over the follow-up year, a fact now recognised in many studies that include a maintenance phase, including the present study albeit rather shortened due to time restrictions.

The National Institute of Mental Health Treatment of Depression Collaborative Research Program (NIMH-TDCRP; Elkin *et al.* 1989) strongly supported the efficacy of IPT for the acute treatment of depression in out-patients. This study, one of the most ambitious acute treatment studies to date, randomly assigned 250 depressed out-patients across 3 research sites with four treatment conditions i.e., 3 (research sites) x 4 (treatment conditions) factorial design with patients randomly assigned to 16 weeks of either:

1. Cognitive Behaviour Therapy (CBT; Beck, Rush, Shaw, & Emery, 1979)
2. Interpersonal Psychotherapy (IPT)

3. Imipramine plus Clinical Management (IMI-CM)
4. Pill-placebo plus Clinical Management (PLA-CM)

Manuals were used to define each treatment and independent adherence monitors rated tapes of sessions to ensure that therapists delivered the treatment according to the manual (Elkin *et al.* 1989). Imipramine and placebo were each accompanied by Clinical Management (CM).

The results demonstrated that most subjects completed at least 15 weeks or 12 treatment sessions, with IPT having the lowest attrition rate among the treatments (Elkin *et al.* 1989). The mildly depressed out-patients improved in all the treatments with no overall difference. The results however did demonstrate differences amongst the more severely depressed out-patients; IMI-CM demonstrated the most rapid response and consistently superior to placebo. IPT was comparable to IMI-CM on several outcome measures and showed a mean outcome superior to placebo. CBT demonstrated an intermediate level of improvement and was not superior to placebo for this group.

There has been controversy with regards to the approach to data analysis and as a result, there have been numerous reanalyses of the NIMH-TDCRP efficacy data (e.g. DeRubeis, Gelfand, Tang, & Simons, 1999; Gibbons *et al.,* 1993; Klein & Ross, 1993; Kung & Elkin, 2000; Zuroff *et al.* 2000). The reanalysis by Klein & Ross showed more distinct differences in efficacy among treatments, especially with the more severely depressed patients. These authors reported that medication was superior to psychotherapy; IPT and CBT were superior to placebo (particularly with the severely depressed); the efficacy of IPT was reported to be superior to CBT among patients with severe illness. The reanalysis is fairly consistent with results reported by Elkin *et al.* (1989) but sharpens differences among treatments. There has however been controversy regarding the reanalyses, as an example, comments have been made regarding the competency of the CBT therapists across all sites involved in the TDCRP and suggestions that the competency differences would account for the differences found between CBT and IPT (Shaw *et al.* 1999). Indeed, Shaw *et al.* (1999) examined the relationship of therapist competence to the outcome of CBT and provided support for the relationship of therapist competence to the reduction of depressive sympomatology. These findings only relate to those patients receiving CBT but do suggest that more positive results might have been obtained for CBT condition in the TDCRP had the therapists maintained a highly competent level of performance on more cases (Shaw *et al,* 1999).

Gibbons *et al.* (1993) further analysed the data and concluded from their reanalysis that across the 16-week course of treatment, patients in *all* groups (including PLA-CM), showed considerable improvement. These authors also reported that IMI-CM demonstrated a faster rate of improvement in comparison to IPT and CBT through the 12-week evaluation. However, this difference is no longer significant at 16 weeks. Therefore, across 16 weeks of treatment, IPT and CBT were not significantly inferior to IMI-CM, in alleviating depressive symptoms although they appear to be slower in their rate of response. These authors also reported that there is little support for the specificity of treatment effects between the two psychotherapies, IPT versus CBT. Elkin (1994) suggests that the relative lack of differences among the treatment may be due to the good outcome for the PLA-CM condition, especially with less severely depressed patients.

In an 18-month naturalistic follow-up study of the TDCRP data, Shea *et al.* (1992) reported that the recurrence rate for major depression was high even with acute treatment and therefore that short-term IPT and CBT does not have enduring effects in many cases and so cannot be considered to be effective. Recovery was defined by the presence of minimal or no symptoms following the end of treatment and sustained during follow-up. Of the subjects who had acutely remitted, 30 percent of CBT, 26 percent of IPT, 19 percent of IMI and 20 percent of placebo subjects remained in remission during that time span. At the end of the 16 weeks, among remitters, relapse over the 18-month follow-up period was 36 percent for CBT, 33 percent for IPT, 50 percent for IMI and 33 percent for placebo. It is important to note, however that data from the MTRD study from Frank *et al.* (1990) were not available when Shea *et al.* (1992) made their conclusions with regards to the effectiveness of treatments. On further examination of this study, however, the analyses were limited to dichotomous diagnostic criteria of recovery and relapse which have several limitations:

1. They restrict the evaluation of finer distinctions such as degrees of symptomatic, functional and phenomenological change;
2. Using dichotomous criteria rather than continuous variables, requires substantially larger sample to achieve statistical power.
3. Threshold values for defining recovery and relapse are somewhat arbitrary (Blatt, Zuroff, Bondi, & Sanislow, 2000).

Despite the limitations of use of dichotomous criteria of recovery and relapse to assess therapeutic gain, Shea *et al.* (1992) found substantial differences at follow up among

treatment conditions. The percentage of patients defined as "fully recovered" among the total sample who began treatment was higher in the two psychotherapy conditions than in the two medication conditions, suggesting better outcome at follow-up in both psychotherapy conditions (Shea *et al.* 1992).

Agosti and Stewart (1998) further analysed the TDCRP data for those patients who responded to treatment and subsequently "recovered" in order to compare their social functioning and symptoms with that of community samples. They concluded that the two groups (recovered versus community sample) were indistinguishable, suggesting that patients who benefit from treatment and recover from major depression can expect to achieve a normal level of functioning and symptomatology, however, they did not identify which arm of the study the 'recovered' individuals came from. If we apply the definition of Shea *et al.* (1992) of "fully recovered", a higher percentage came from the two psychotherapy conditions and therefore it would appear that the conclusions of Agosti and Stewart (1998) are applicable to the two psychotherapy conditions to a greater extent than to the medication conditions.

Blatt *et al.* (2000) recently analysed the TDCRP data stating that they considered that it was premature to draw conclusions about the relative efficacy of IMI-CM (as Elkin 1994: Klein and Ross, 1993) until a comprehensive assessment was conducted at termination and follow-up on the broad range of measures available (including evaluation of symptoms, functional capacities and reports by patients about their satisfaction with the treatment they received and the impact on their lives, particularly after a substantial period following termination). They concluded that analyses of the various measures of therapeutic gain during treatment, at termination and at 18-month follow up indicate that medication (IMI-CM) results in a significant reduction in symptoms at mid-treatment (eighth week) in comparison to CBT and IPT, as well as placebo (e.g. Klein and Ross, 1993), but this relative advantage for medication is markedly diminished at termination (e.g. Shea *et al.*, 1992; Watkins *et al.* 1993). The significantly greater reduction of symptoms at mid-treatment in the active medication condition (IMI-CM) has led in the past, to a number of investigators (e.g., Elkin *et al*, 1985, 1989, 1995, 1996; Klein and Ross, 1993) to conclude that medication was more effective than CBT and PLA-CM and somewhat more effective than IPT in the brief outpatient treatment of major depression, especially for more severely depressed patients. The three active treatments however, were not significantly different at termination in Blatt *et al.*(2000) study using the ratings by therapists and patients at termination.

Blatt *et al.* (2000) also concluded that at 18-month follow-up, patients reported significantly greater overall satisfaction with treatment and patients in both IPT and CBT reported significantly more constructive effects on life adjustment than the patients in the two medication conditions did. Patients in the two psychotherapy conditions thought that treatment had significantly greater effects on helping them to establish better interpersonal relationships, to cope with those relationships more effectively and to recognise more fully their symptoms of depression than patients in the IMI-CM and PLA-CM.

It is possible, of course, to place different interpretations on the results of Blatt *et al.* (2000). As an example, it may be the consequence of cognitive dissonance because of more effort involved in psychotherapy than in medication. Blatt *et al.* (2000) study highlights the important question of having an exclusive focus on symptom reduction to evaluate therapeutic gain, as discussed earlier. Blatt *et al.* (2000) report consistent and significant differences among treatment groups in the effects of treatment of life adjustment at follow-up.

The research evidence therefore suggests that IPT and CBT are effective acute treatments for depression. Based on measures of therapeutic gain, IPT appears to generate greater overall satisfaction than IMI-CM or PLA-CM and appears to have a greater effect on life adjustment than either pharmacotherapy or placebo (Blatt *et al.* 2000).

In an attempt to make a useful application of all the outcome research, as described for the NIMH TDCRP above, Ogles, Lambert and Sawyer (1995) evaluated the **clinical significance** of the results. They reported that a substantial number of patients who received treatment for depression made reliable improvements and had post-treatment scores that fell within a functional distribution (as defined by Jacobson and Truax, 1991). They also reported that there were no differences in clinical significance rates among the treatment groups for measures of depressive symptoms but when considering general improvement, treatments did differ. When the completer sample were examined (as described later), the highest proportion of patients who met criteria for clinically significant change came from the IPT group (85 percent of the total).

1.62 Efficacy of IPT as a Maintenance Treatment for Depression (IPT-M)

The MTRD study was a 3-year randomised outcome trial in depressed patients with a clear history of repeated episodes of depression (Frank *et al.* 1990). Patients were randomised to

IPT-M with maintenance pharmacotherapy (imipramine), combination pharmacotherapy/ psychotherapy, and a control group. IPT-M was designed specifically to maintain recovery and reduce vulnerability to future episodes by improving social adjustment. All subjects received treatment from the acute episode of depression with a combination of IPT and imipramine and were continued on that combination until they had sustained a state of remission defined as having a HRSD score as less than or equal to 7 for 20 weeks. After achieving that status, patients were randomly assigned to one of five maintenance treatments: (1) IPT-M alone; (2) IPT-M with placebo tablet; (3) IPT-M with imipramine; (4) medication clinic visits with imipramine or (5) medication clinic visits with placebo tablets.

The study demonstrated that when patients received a combination of pharmacotherapy and IPT, those who continued to receive IPT on a monthly basis following drug discontinuation, remained well significantly longer than those who did not. Frank *et al.* (1990) reported that this result demonstrated a clinically significant and meaningful effect for IPT-M. Frank *et al.* (1991) provided a follow-up report from this study, which established the value of maintenance treatment in the prevention of recurrence of major depression and found IPT-M to have significant prophylactic capacity, even when used at a very low dose.

Therefore, from the results of the MTRD study (Frank *et al.* 1990) and the NIMH Collaborative Study (Elkin *et al.* 1989) it can be clearly stated that the performance of IPT in the treatment of clinical depression, consistently surpasses no treatment and placebo therapy in both acute and maintenance treatment of outpatients with depression.

1.7 WHY IS IPT EFFECTIVE?

The following section attempts to answer the question of why IPT might be effective through examination of research conducted to date involving: patient predictors; therapist factors; the therapeutic alliance and perfectionism.

Through the numerous outcome studies, as outlined above (Elkin *et al.* 1989; Frank *et al.* 1990), IPT has been demonstrated to be effective. Outcome studies, however, do not reveal how the treatment works or how patients recover from an acute episode of depression or how protection from a recurrence of symptoms may occur. A brief review of the major findings demonstrates that the following factors may be particularly salient in answering the question of why IPT may be effective.

1.71 Patient Predictors

In an analysis of the TDCRP data, Sotsky *et al.* (1991) found that patients with a low baseline level of social dysfunction responded well to IPT whereas those with severe social deficits responded less well to IPT. Patients with greater symptom severity and difficulty in concentrating responded poorly to CBT (Sotsky *et al.* 1991). Furthermore, Sotsky argued that high initial severity of depression and impairment of functioning predicted superior response to IPT and to IMI. This is an extremely important point therapeutically, as in Primary Care, patients may be referred specifically for IPT, if the General Practitioner perceives there to be interpersonal deficits and yet the research conducted by Sotsky *et al.* (1991) quite clearly demonstrates that **HIGH** social dysfunction predicts a poorer response to IPT.

As discussed earlier, not only does the marital relationship have a high correlation with and etiological implications for the onset of depression; its effects on patients' responsiveness to treatment and the maintenance of treatment gains have also been demonstrated (Rounsaville, Weissman, Prusoff and Hercet-Barob, 1979; Rounsaville, Prusoff and Weissman, 1980). Kung and Elkin (2000) recently examined the impact of marital adjustment on depressed married patients in the context of individual treatment (using the NIMH TDCRP dataset). Their results indicated that patients' level of marital adjustment at termination and the extent of marital improvement over the course of treatment significantly predicted treatment outcome at follow-up in terms of both depressive symptoms and social functioning. Marital adjustment at intake was not a significant predictor of depressive symptomatology at termination and follow up. However, more relevant to the present discussion, neither treatment modality (IPT or CBT) nor the interaction between treatment and pre-treatment marital adjustment significantly predicted the outcome measures, including marital adjustment at termination or follow-up.

1.72 Therapist Factors

Frank, Kupfer, Wagner, McEachran & Cornes (1991) discovered that the ability of the therapist to keep sessions focused on interpersonal issues was significantly correlated with prevention of relapse in their maintenance study of IPT for recurrent depression. Frank *et al.* (1991) reported that the patients who received monthly IPT with a high interpersonal specificity survived a mean two years before depression recurred whereas those patients who received therapy with a low interpersonal focus were afforded only 5 months of protection before relapse. In the present study, this finding was acknowledged, all therapy sessions

were audio-taped and adherence to the present adaptation of IPT was rated by an experienced IPT therapist (KC).

1.73 Therapeutic Alliance and Perfectionism

More recently, Zuroff *et al.* (2000) re-examined the TDCRP dataset for the relationship among perfectionism, perceived relationship quality, and the therapeutic alliance. These authors demonstrated that (a) the patient contribution to the alliance and the perceived quality of the therapeutic relationship were independent predictors of outcome, (b) perfectionistic patients demonstrated smaller increases in the Patient Alliance factor over the course of treatment and (c) the negative relation between perfectionism and outcome was explained by perfectionistic patients' failure to develop stronger therapeutic alliances. The authors found no evidence that the results were moderated by treatment condition. Therefore, the roles of perfectionism and the therapeutic alliance were not demonstrably different in the CBT or IPT groups. The study could be criticised for the measure of perfectionism used, the Perfectionism sub-scale of the DAS. It would also be interesting to determine whether similar results would have been obtained if the perspective of the patient, therapist and observer had all been utilised.

Therefore, from the above, it can be concluded that IPT is equivalent in efficacy to well controlled pharmacotherapy in bringing about a remission of depressive symptoms and has been adapted to other disorders and to alternative formats as is discussed below.

1.8 ADAPTATIONS OF IPT

The following section is dedicated to a description of the various forms of adaptations of IPT, many of which are still in their infancy, with only pilot data available to suggest whether the adapted format is feasible. Where available, efficacy data has been included in the description.

1.81 IPT and Mood Disorders

In terms of mood disorders, IPT has been adapted for Recurrent Major Depression (IPT-M) and Dysthymic Disorder (IPT-D). IPT-M is a monthly maintenance form of IPT (Frank, 1991) which differs from acute IPT in that it is scheduled to continue once a month, for 3 years; the aim is to delay or prevent relapse. Therapists and patients can choose to shift amongst the four focus areas, rather than adhering to a particular focus (Frank, 1991). The study conducted by Frank *et al.* (1991) demonstrated that even in an extremely high risk

group, a monthly dosage of IPT-M provides an average of a year and a half of protection against recurrence.

IPT-D was developed by Markowitz (1998) for dysthymic disorder and was considered to be important for several reasons including the observation that approximately half of those diagnosed with dysthymic disorder, do not respond to antidepressant medications (Markowitz, 1994). IPT-D was developed to confront the interpersonal difficulties that are so prominently a part of the disorder and to help patients to develop their social skills whilst alleviating their tenacious mood disorder. In this adaptation, patients are encouraged to re-conceptualise what they have seen as their lifelong character flaws as ego-dystonic, chronic mood-dependent symptoms as chronic "state" rather than "trait". There is no efficacy data as yet from clinical trials although there are trials underway for IPT-D (Steiner *et al.* 1998). Pilot data has been reported as being positive, in terms of reducing symptoms of depression, and has been associated with significant economic savings in direct use of health care and social services in the US (Steiner *et al.* 1998).

IPT has been adapted for different groups of patients presenting with Major Depression such as: older adults (Reynolds *et al.* 1999); adolescents (Moreau, Mufson, Weissman and Klerman, 1991; Mufson, Weissman, Moreau and Garfinkel, 1999;); medically ill (Stuart & Cole, 1996); ante and post-partum (Stuart, 1999) and HIV (Markowitz, Klerman & Perry, 1993). Some of the research, which has adapted IPT, has adapted the manual in order to meet the psychosocial needs and problem areas of specific populations. As an example, Mufson, Moreau, Weissman and Klerman (1993) modified IPT to incorporate adolescent developmental issues (IPT-A) and added a fifth problem area of the single-parent family, an interpersonal situation found frequently among adolescents (Appendix 3.0 for specialised manuals).

1.82 Use of IPT in Other Diagnostic Areas

Following the demonstration that IPT is effective in the treatment of mood disorders, the therapy has been expanded to other diagnostic areas such as the following:

1.821 Eating Disorders

- **Bulimia Nervosa**

Fairburn *et al.* (1991, 1993, 1995) altered IPT for two studies of bulimic patients. The research demonstrated that IPT had long-term benefits, which were comparable to CBT and

superior to a behavioural control condition. Although the patients in the CBT group showed initial advantages (Fairburn *et al.* 1991), over time patients in CBT and IPT made equivalent and substantial changes across all symptom domains (Fairburn *et al.* 1993). At one-year follow-up, IPT and CBT demonstrated equal efficacy, with each superior to BT. In the first trial of IPT for bulimia nervosa, there was no significant adaptation of the original model of IPT and eating problems were *not* addressed in the therapy (Fairburn, 1993). The bulimia nervosa was diagnosed as a medical illness and then linked to an interpersonal problem area in a formulation.

- **Anorexia Nervosa**

McKenzie, Bulik, McKenzie, Luty and Jordan (2000) have developed IPT for outpatients with a diagnosis of anorexia nervosa, in a similar way to Fairburn *et al.* (1995) for bulimia nervosa, as described above. The four problem areas and IPT strategies remain unchanged in IPT for anorexia nervosa; to date there is no efficacy data available.

- **Binge Eating Disorder**

Wilfley *et al.* (1993) have adapted IPT for Binge Eating disordered patients in a group format. In their initial study, Wilfley *et al.* (1993) demonstrated that group treatment using either CBT or IPT was more effective than a waiting list control, in terms of reducing the binge eating. Results were sustained at a one-year follow-up.

1.822 Substance Related Disorders

IPT cannot be claimed to efficacious in treating patients with substance misuse problems or substance dependence. There have been two trials to date with substance abusers, both of which failed to demonstrate efficacy. The first trial was conducted by Rounsaville, Glazer, Wilber, Weissman and Kleber (1983) who found recruitment difficulties and high dropout rates. Symptomatic improvement was not specific to IPT when compared to standard treatment for opiate users on methadone maintenance (Rounsaville *et al.* 1983). In a separate trial Carroll, Rounsaville, and Gawin (1991) discovered that 12 weeks of IPT was ineffective or marginally worse than Behavioural Therapy (relapse prevention) for cocaine abusers attempting to achieve abstinence (Carroll *et al.* 1991).

1.823 Anxiety Disorders

Modification of IPT is currently being conducted for **Social Phobia** by Lipsitz *et al.* (in press). IPT is also being modified for **Panic Disorder** but as yet there is no efficacy data (Weissman, Markowitz and Klerman, 2000).

1.83 IPT in other Formats

The actual format of IPT has also been altered i.e. from individual psychotherapy to a **group format** (Wilfley, Frank, Welch, Spurrell and Rounsaville, 1998). Interestingly, until Wilfley *et al.* (1998) proposed a set of questions to act as a template for making adaptations of manualised treatments, no research literature or formal guidelines existed.

"...our questions and our solutions are generalisable and will be useful to other clinical researchers undertaking the process of adaptation."

Wilfley *et al.* (1998) p380

Other formats include IPT by telephone (Donnelly *et al.* in Weissman, Markowitz & Klerman, 2000) however, the authors report the limitations of such an approach and suggest that the efficacy is pending. A patient guide has also been developed (Weissman, 1995) which includes worksheets and is presented in a user-friendly manner; the authors again report that there is no efficacy data for use of such a manual.

Conjoint IPT for depressed patients with marital disputes (IPT-CM) has been developed by Foley (1990). Results from a pilot study of IPT-CM (IPT versus IPT-CM) demonstrated that both groups of patients improved equally in symptoms and in social adjustment but those who received IPT-CM showed greater improvements in marital adjustment and affectional expression than did patients receiving IPT. The results from this pilot study however should be read with caution due to the nature of the design, for example, the small sample size, the lack of no-treatment control group, and the absence of an alternative psychotherapy of proven efficacy.

IPT has also been adapted to a form known as Interpersonal Counselling (IPC, Klerman *et al.*, 1987; Weissman, 1993), a brief treatment (six 30 minute sessions) focused on the patient's current psychosocial functioning and administered by health care professionals (usually nurses.) IPC as a manual has not been published, however, the authors permitted comparison of the IPC manual with the current adaptation (IPT-B) for the present study. IPC was designed for distressed primary care patients who do not meet syndromal criteria for psychiatric disorders. IPC was first tested with medical patients with stress symptoms

(Klerman *et al.*, 1987; Weissman, 1993) demonstrating that when compared to a waiting list condition, the difference in symptom severity post treatment was highly significant. The authors therefore stated that IPC was a feasible intervention with patients presenting to Primary Care with symptoms of distress and could be delivered by non-mental health nurse practitioners.

1.84 Summary

IPT is a system of brief focal psychotherapy that has incorporated the theoretical positions of Meyer, Sullivan and Bowlby as well as the empirical evidence linking differences in the immediate social environment with the onset of depression. The IPT approach to understanding and treating depression integrates the psychoanalytic perspective, which emphasises childhood experiences with the cognitive behavioural perspective, with its emphasis on current psychosocial stressors and ongoing difficulties. IPT has been adapted and used successfully within different disorders and across different treatment modalities.

1.9 CONTEXT FOR THE PRESENT STUDY

The following section describes the context for the present study with an outline of the main research questions, aims and hypotheses.

Within Primary Care (in Fife, Scotland) patients treated for depression are seen for an average of 6-8 sessions, mainly using the Cognitive Behavioural Model for Depression (Beck *et al.* 1979). As stated, IPT is a manualised treatment (Klerman *et al.* 1984) and calls for 16 sessions, usually taken over 20 weeks. If therapists are to remain true to the model, does that therefore restrict its use within Primary Care as patients are, on average, only seen for 6-8 sessions? If IPT can be used in a briefer format to fit in with current practice does it retain its efficacy?

It is interesting to note that one session per week for 12-20 weeks has become an industry standard for the "short-term" psychotherapy of depression, however there is little empirical evidence to support this particular format of therapy, regardless of the theoretical model being employed. Indeed, Shapiro *et al.* (1994) have demonstrated that both mildly and moderately depressed clients had equivalent, strongly positive outcome **regardless of whether they had been allocated 8 or 16 sessions** of either cognitive-behavioural or psychodynamic-interpersonal psychotherapy, however, this same standard has NOT been applied to the adaptation of IPT.

1.91 Primary Care Guidelines for Major Depression

In recent years there have been efforts made to establish criteria against which the status of psychological interventions is measured (Chambless, Baker, Baucom, Beutler, and Calhoun, 1998; Woody & Sanderson, 1998). In the UK, the intention is to devise clinical guidelines and training and accreditation protocols, which are increasingly consistent with the evidence base (Department of Health, 1998). The grading of evidence to be apportioned to each study is based on the efficacy paradigm, which holds the randomised-controlled trial as its gold standard. In 1996, NHS Strategic Review, *Psychotherapy Services in England*, set out a programme for co-ordinated, evidence based, comprehensive, safe and equitable provision of psychotherapy and pointed to the gap between these ideals and reality. The department of Health recently (February 2001) published the *'Treatment Choice in Psychological Therapies and Counselling Evidence Based Clinical Practice Guidelines'* in which recommendations were made with reference to the treatment of depression stating:

'Depression may be treated effectively with cognitive therapy or ***interpersonal therapy****. A number of other brief structured therapies for depression may be of benefit, such as psychodynamic therapy...CBT and IPT effectively reduce symptoms of depression'* (p2)

The above statement was weighted according to Level A criteria, i.e. *'Based on consistent finding in a majority of studies in high quality systematic reviews or evidence from high quality studies'* (p1). However, no indication was given as to how many sessions would be effective and for what degree of severity of depression.

The American Psychiatric Association have recently revised their treatment guidelines for the treatment of major depression (American Psychiatric Association, 2000) and become more influenced and driven by the empirical literature. In an evaluation of the scientific basis for the guidelines, it is noted that the efficacy of cognitive behaviour therapy and **interpersonal psychotherapy** have been particularly well documented by the research literature. The guidelines were influenced by more than 80 controlled trials of cognitive behaviour therapies which were generally reported to be superior to minimal treatment controls and at least as effective as other interventions to which they were compared (Gaffan, Tsaousis & Kemp-Wheeler, 1995). The US guidelines also state that although interpersonal psychotherapy has been tested in a smaller number of studies, it has consistently outperformed control conditions and done at least as well as other interventions (Jarrett & Rush, 1994; Rush and Thase, 1999).

The US guidelines are organised into 3 parts with the first part being an overview of the major treatment recommendations for acute treatment (resolution of symptoms), continuation treatment (prevention of relapse) and maintenance treatment (prevention of recurrence). The second part contains information on the nature of depression, including its diagnosis and distribution in the population. There is also a review of the published literature regarding the available treatments for depression with separate sections on drugs and psychotherapy and combined treatment. The final part of the guidelines describes where more research is needed to guide clinical decisions regarding treatment.

The guidelines do include recommendations for the selection of the initial modality of treatment to be influenced by factors such as symptom severity and patient preference. It further advises that at least some psychosocial interventions can be considered as the sole treatment for patients with mild to moderate depression, but that medications or ECT should be provided for patients with moderate to severe disorders. The guidelines also state that preference should be given to those psychosocial interventions that have been shown to be effective and notes that efficacy has been particularly well documented for cognitive behaviour therapy and interpersonal psychotherapy.

It is interesting to note that the guidelines recommend assessing the adequacy of response within 4 to 8 weeks and either altering or changing the nature of treatment in the event that the response is less than complete but offers little direct guidance for the practice of the psychosocial interventions.

Neurolink[1] recently published the *"Depression Guidelines: Recognition and Management in General Practice."* The purpose of such is to provide GPs, and other healthcare professionals in Primary Care, with key information points in order to improve the recognition of depression and facilitate better management. Neurolink Guidelines state IPT to be *"as effective as CBT in mild to moderate depression...it requires the same amount of time as CBT" (p23).* The Guidelines also state that CBT involves 8-16 hours and suggests studies that demonstrate that mild depression responds in 6-8 sessions. The Guidelines, however, do not cite any reference for this statement.

[1] Neurolink is an independent board of mental health experts supported by an educational grant from Wyeth Laboratories since 1995.

1.92 The Second Sheffield Study (Shapiro et al. 1994)

In a study of 117 depressed clients, stratified for severity, who completed 8 or 16 sessions of manualised treatment, Shapiro *et al.* (1994) demonstrated an equal effectiveness when comparing a cognitive-behavioural (CB) intervention versus psychodynamic-interpersonal psychotherapy (PI), irrespective of the severity of depression or duration of treatment. The authors reported that there was no overall advantage of 16 sessions treatment over 8 sessions except in those presenting with relatively severe depression, who improved substantially more after 16 sessions.

Shapiro *et al.* (1994) provided the present study with justification to determine whether 8 sessions of Interpersonal Psychotherapy for Depression (IPT) was effective in terms of reducing the presenting symptoms of depression and improving the quality of interpersonal relationships when compared to a waiting list control group.

Taking the above into account, the overarching research question was as follows:

Can Interpersonal Psychotherapy of Depression (IPT) be adapted to be briefer (IPT-B) within a Primary Care setting and still remain effective in terms of reducing the symptoms of depression and improving the quality of interpersonal relationships?

1.93 Research Questions

1. Compared to waiting list control, does IPT-B for depression produce significant improvement in depressive symptomatology?

2. Compared to waiting list control, does IPT-B for depression produce improved quality of interpersonal relationships?

3. Compared to waiting list control, does IPT-B for depression remain effective over time?

1.94 Aims and Hypotheses of the Present Study

1. **To determine whether IPT-B is effective in reducing the symptoms of depression when compared to waiting list control.**

Research Hypothesis 1: The adapted version of IPT to IPT-B is effective in reducing the symptoms of depression when compared to waiting list control.

2. **To determine whether IPT-B is effective in improving the quality of interpersonal relationships when compared to waiting list control.**

Research Hypothesis 2: The adapted version of IPT to IPT-B is effective in improving the quality of interpersonal relationships when compared to waiting list control.

3. **To determine whether IPT-B is effective over time (using the same criteria for effectiveness i.e. reduction for symptoms of depression and improvement of quality of interpersonal relationships) when compared to waiting list control.**

Research Hypothesis (3a): The adapted version of IPT to IPT-B is effective over time (10 weeks and 20 weeks post Baseline Assessment) in terms of reducing symptoms of depression and (3b): improving the quality of interpersonal relationships when compared to waiting list control.

1.95 The Stages of the Present Study

1. Adaptation of IPT to IPT-B (adhering to the suggestions of Wilfley *et al.*1998).

2. Development of the IPT-B Manual according to Klerman *et al.* (2000; Appendix 4.0).

3. Tested out on a Single Case Study (Appendix 5.0) in which *results demonstrated an overall considerable improvement in terms of a reduction in symptoms of depression and an improvement in the quality of interpersonal relationships over the course of treatment.*

4. The results from the Single Case study provided justification for conducting the present 2 group randomised study with a larger population of N as follows:

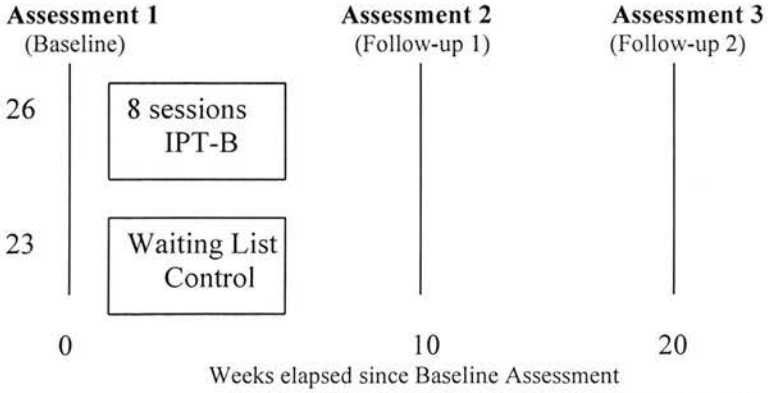


Figure 1.0 Design of the Present Study.
IPT-B = Interpersonal Psychotherapy for Depression - Brief Version

CHAPTER 2.0

METHODOLOGY

CHAPTER 2: METHODOLOGY

2.1 ADAPTATION OF IPT TO IPT-B: *Brief overview of the process from single case study to the present experimental v's control group design.*

The present study aimed to determine whether a briefer version of Interpersonal Psychotherapy for Depression (IPT-B) is effective in reducing symptoms of depression and improving the quality of interpersonal relationships in patients presenting to Primary Care with Major Depressive Disorder (MDD). In order to achieve these aims, it was necessary to determine whether IPT could be adapted to a briefer version i.e. IPT to IPT-B and then to determine whether the new brief version was effective in achieving the same aims within a single case. As a preliminary step to the present study, a pilot study was conducted, which involved the adaptation process (the original model of IPT to IPT-B) and application utilising a single-case study design. The preliminary stage was consistent with advice provided by the original authors of IPT. Indeed, the most recently published book by Weissman *et al.* (2000) devotes a section on "How to Develop a Treatment manual." Even though that advice was published a year *after* the original pilot study, the present study does adhere to the recommendations. (Appendix 4.0 describes the steps as suggested by Weissman *et al.* (2000) and the present author's response). A detailed description of the preliminary stage of the study, the single-case pilot study, is provided in Appendix 5.0.

2.11 The Intervention used: Adaptation of IPT to IPT-B

In adapting an individual treatment to an alternative format (i.e. IPT to IPT-B), the central consideration was how best to **preserve the hypothesised curative elements** of the manualised treatment whilst accommodating to the constraints imposed and opportunities provided by the changed time limits (Wilfley *et al.* 1998).

Wilfley *et al.* (1998) suggest that the elements which *presumably* constitute the active ingredients must be identified. A consideration must also be made as to how the altered therapeutic time may affect the delivery. Wilfley *et al.* (1998), in their discussion of the provision of a standardised format for adapting manualised treatments[2], suggest that the following questions should be asked:

[2] Wilfley *et al.*, (1998) presented a paper on their adaptation of IPT from individual treatment to group treatment and from MDD to BED. The questions posed in this section relate to their adaptation across modalities, i.e. from individual treatment to group treatment.

1. ***What are the effective change processes of the individual treatment and how will they be preserved in the altered format?***
2. ***How are the therapist and patient roles characterised in the individual treatment and how will they be maintained in the [new] format?***
3. ***What are the techniques of the individual treatment and how will they be delivered in a [shortened] format?***

The questions raised above were all taken into consideration when examining the differences and similarities and subsequent adaptation of IPT to IPT-B (Appendix 6.0 and 6.1).

The adapted format of IPT to IPC (Interpersonal Counselling, Weissman, 1993) was used as a comparison in both the pilot study and the present study, as IPC is the closest in style and format to the abbreviated IPT-B model. IPC has not yet been published but the author (Weissman, M.M.) kindly allowed comparisons to be made under the conditions that IPC would not be copied, revised or renamed. Due to the restrictions, only general comparisons appear in the current paper, however, detailed comparisons were made in order to adhere to Wilfley's suggestions as noted above (Appendix 6.2).

Although the single-case pilot study had a number of attractive features, such as being conducted fairly quickly and within routine clinical practice, the results of such a design can be criticised for the potential difficulty of generalisation to a broader clinical population. The results of the single-case pilot study, however, provided valuable justification for exploring the abbreviated model of IPT further. The contrast of the **waiting list control group** was required in order to be clear that any demonstrated benefits could be attributed to the intervention. There are however criticisms of the present approach, which includes a control group, as outlined in Chapter 4.0: Discussion.

2.2 FROM SINGLE CASE TO LARGER N PRESENT STUDY

2.21 Present Design

"The art of outcome research design becomes one of creative compromises based upon explicit understanding of the implications of the choices made."

Shapiro (1989) p164

The present study employed a randomised 2-group experimental versus control pretest-posttest design: IPT-B Treatment versus waiting list control group. In 1997, Wampold

highlighted the distinction between **efficacy** studies and **effectiveness** studies. The former applies to:

> *"..well-controlled outcome research in which treatment groups are compared either to control groups and/or to other treatment groups under experimental conditions."*
>
> (Wampold, 1997 p22)

Effectiveness studies on the other hand assess:

> *"..whether patients benefit from psychotherapeutic treatments under the conditions found in settings where psychotherapy is actually administered by practitioners. Effectiveness studies are essentially an assessment of outcomes of psychotherapy in uncontrolled field settings"*
>
> (Wampold, 1997 p22)

In order to ensure that internal validity[3] is achieved within an efficacy study, techniques rarely used in clinical practice are employed including the following:

1. studying highly selected, diagnostically homogenous patient populations;
2. randomisation of patients into treatments;
3. employment of extensive monitoring of patients' progress

The above techniques however, may also pose a threat to *external validity*, i.e. the extent to which we can infer that the causal relationship can be generalised.

The bridge between research trials and routine treatment is even more difficult to span because of the vicissitudes of biology and individual psychological differences in treatment response (Roth and Fonagy, 1996). As psychotherapy is a highly complex process, any number of interacting factors could be significant to outcome but the priority of the present research was to show an underlying causal relationship between improvement and intervention (IPT-B). Realistic controls therefore were employed with regards to:

1. treatment structure and administration
2. sample selection
3. outcome assessment

2.22 Present Sample

Referrals for the present study came from three Clinical Psychologists attached to five Primary Care Out-Patient practices in West Fife. All patients who were referred to the

[3] The extent to which a causal relationship can be inferred among variables, or where the absence of a relationship implies the absence of cause.

Department of Clinical Psychology, with a possible primary diagnosis of depression, were referred to the study and assessed by the present author to determine their eligibility for inclusion in the current study.

2.23 Entry Criteria

The sample was specified in terms of the inclusion and exclusion criteria, known collectively as the entry criteria as follows:

1. Informed consenting adults between 18 and 65 years.
2. All participants who met the following criteria:

- DSM-IV Diagnostic Criteria for Major Depressive Disorder as judged by the Structured Clinical Interview for DSM-IV (SCID: First, Spitzer, Gibbon and Williams, 1997).
- Diagnosis of depression as rated by Revised Hamilton Rating Scale for Depression (RHRSD) and the Beck Depression Inventory-II (BDI-II). Severity was defined in terms of cut-off scores on the pre-screening instruments.
- No depressive disorder severe enough to require immediate treatment.

3. All Participants considered depressive symptoms as their main problem.
4. All Participants were willing to accept random allocation including the Waiting List for Treatment as Usual condition.
5. No evidence of organic mental disorder, schizophrenia, alcohol or drug dependence.
6. Concurrent Axis-II personality disorder was not a reason for exclusion unless the personality disorder was clearly the primary problem.
7. Concurrent Axis-I anxiety diagnosis was not a reason for exclusion unless the anxiety disorder was clearly the primary problem.
8. Participants who did not fulfil the entry criteria or who dropped out after randomisation were offered treatment as usual at the Clinical Psychology Department.
9. Participants prescribed antidepressant medication agreed to remain on a stable regimen throughout the duration of the study.
10. Participants who met selection criteria and agreed to enter the trial were assigned at random, using the sealed envelope technique, to one of 2 conditions:

A. **Immediate start IPT-B** (treatment group) Patients were offered a series of appointments to begin immediately post assessment with 2 follow-up appointments at end of treatment and 2 months post end of treatment.

B. **Waiting List for Treatment as Usual** (control group) within the Clinical Psychology Department. Patients were replaced on the waiting list where they had come off and waited for the same amount of time for treatment as usual within the Department.

Patients in this condition were given 2 follow-up assessment appointments at 2 and 4 months post baseline assessment. Patients in this group would not have had any contact with the Clinical Psychologist due to normal waiting times but would have been free to contact their GP for any routine care.

Patients in both groups were asked to maintain a diary over the course of the study to determine contact with any other professional, in order to minimise effects from any external source.

2.24 The Issue of Blinding

In many clinical trials of treatment, where there is some subjectivity in both disorder definition and quantification of response, it is necessary to make the assessment of response as objective as possible. In practice, this is helped by masking or blinding the assessor to the identity of the allocated treatment. The current trial made no attempt to disguise the nature or form of treatment to the patient and due to the design limitation (assessor and therapist being the current author) group allocation was open to the assessor.

2.25 Randomisation

On entry to the trial, patients were allocated a trial number, which served as a unique identifier on all records. The present trial utilised the **sealed envelope technique** (Gore, 1981) in which each envelope contained a card labelled with the same information as the corresponding envelope together with the identity of the treatment allocated. Envelopes were kept and opened in strictly increasing order of the serial numbers in each group; only one envelope was used per patient and was opened only after the decision to randomise treatment.

2.26 Measures of Outcome

Morley's Assessment-Evaluation Funnel (Morley, 1989:Appendix 7.0) was used to prospectively assess participants in both groups, at specified intervals, using multiple measures of outcome appropriate to the disorder and to the goals of the treatment method (Shapiro *et al.* 1994).

2.261: Structured Clinical Interview and Revised Hamilton Rating Scale for Depression

In order to satisfy the demand for a *standardised diagnostic measure* and *objective measure* (Shapiro *et al.*1994) the **Structured Clinical Interview for DSM-IV** (SCID, First *et al.*.

1997) and the **Revised Hamilton Rating Scale for Depression** (RHRSD, Warren 1994) were employed. Both versions of the RHRSD were used i.e. the Clinician Rating Form (RHRSD-CV) and Self-Report Problem Inventory (RHRSD-PI). The total score on both versions of the scale reflects the severity of depression and allows a confirmation or disconfirmation of a diagnosis of Major Depressive Disorder. The RHRSD takes the form of a clinical interview whilst the problem inventory is a self-report booklet which takes approximately 15 minutes for the patient to complete, evaluating symptoms in the same domains as the clinician-rated scales but in a true/false format. The problem inventory has a reading age of approximately 11 years.

The original Hamilton scale (Hamilton, 1960) has often been reported to be the most sensitive scale for measuring response to treatment and is probably the most widely used scale in research on depression for describing levels of severity in different groups, to ensure an adequate matching or to measure improvements in trials on treatment[4]. In order to retain the relationship of the RHRSD to the research which has already been conducted on the original Hamilton Scale, the RHRSD is constructed around the 17 original items. Items which have been added to the revised version are as follows: three items relating to the cardinal diagnostic indicators of depression plus five items designed to assess the significance of symptoms in the area of social functioning.

The internal consistency of the RHRSD, as reflected by Cronbach's alpha, for the Clinician Rating Form has been reported as 0.79 for the verification sample and 0.81 for the Self-Report Problem Inventory (Warren, 1994). The level of reliability for each format of the scale is reported as being consistent, with estimates of internal consistency ranging from 0.45 to 0.95 (Hedlung and Vieweg, 1979). The interrater reliability has been reported as being high, ranging from 0.52 to 0.96 (Hedlung and Vieweg, 1979).

Warren (1994) reports that a posttreatment RHRSD Total Score of 10 or less or a decrease by more than one-third in the initial severity level of the RHRSD Total Score is considered to represent successful treatment response over the short term. The reduction in the RHRSD Total Score must be maintained over the course of 6 months or more before an individual can be considered to have recovered.

[4] Zitman, Mennen, Griez and Hooper (1989) present a report in which they state that fewer than half of the researchers whose published research they examined had actually used the form of the rating scale to which they referred their readers. Out of 50 research centres, these authors could not identify two that had used exactly the same version of the scale.

2.262 Beck Depression Inventory-II

In order to satisfy the demand to be as *specific as possible to the treatment being evaluated* and for *self-report measures* (Shapiro *et al.*1994) the following measures were employed: **The Beck Depression Inventory II** (Beck *et al.* 1996). The BDI-II consists of 21 items, which assesses the **intensity** of depression in both clinical and normal clients. Each of the 21 items is arranged with a choice of 4 statements in increasing order of severity about a particular symptom of depression. Each item is rated on a 4-point scale ranging from 0 to 3. The maximum score is 63. The scale includes items which update the older version (BDI, Beck *et al.* 1961) to the current diagnostic criteria of DSM-IV (APA, 1994). The older version was based on the past 7 days, however, in line with DSM-IV, the time frame for the BDI-II has been increased to the past 2 weeks. According to the authors of the BDI-II, this version shows improved clinical sensitivity with a reliability of the BDI-II being higher than the BDI (Coefficient Alpha = 0.92 for BDI-II and 0.86 for BDI; Beck, Steer and Brown, 1996).

2.263 World Health Organisation Quality Of Life Scale –Bref version

The **World Health Organisation Quality of Life Scale** (WHOQOL Group, 1996). The measure of quality of life responds not only to one of the overarching aims of IPT-B but also as a response to the call for data on quality of life (Gladis, Gosch, Dishuk, and Crits-Christoph, 1999). In their review of the controversies and evidence in empirically supported psychological interventions, Chambless and Ollendick (2001) suggest that quality of life measures will become the central outcome measure in future trials.

The WHOQOL-Bref was used to establish baseline scores and to examine changes in quality of life over the course of the IPT-B Treatment. Quality of life is defined as follows:

> *"Individuals' perceptions of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns."*
>
> World Health Organisation (1996)

The WHOQOL is a generic quality of life measure and the abbreviated version the WHOQOL-BREF provides a valid and reliable alternative to the lengthier WHOQOL-100. The pilot study utilised the abbreviated version of the WHOQOL-100.

Since the pilot study was conducted in 1999, further research on the WHOQOL has been reported by O'Carroll, Smith, Couston, Cossar and Hayes (2000) who state that the

WHOQOL-BREF is useful in evaluating quality of life improvement following therapeutic interventions. The 26-item questionnaire, derived from the 100-item parent WHOQOL-100, covers 4 domains of Physical Capacity, Psychological, Social Relationships and Environment. The Social Relationships domain was of primary interest in the present study to examine perceived improvement in interpersonal relationships. O'Carroll *et al.* (2000) suggest that the WHOQOL-BREF can reliably measure changes following therapeutic interventions and that there is adequate test-retest reliability when assessed on a clinical sample. These authors state that the WHOQOL-BREF therefore is satisfactorily responsive to clinically meaningful change for the Physical, Psychological and Environmental domains but there is a significant reduction in sensitivity to change on the Social dimension.

2.264 Significant Others Scale (B)

Significant Others Scale-B version: SOS (Power, Champion and Aris, 1988) assesses four emotional and four practical social support functions in significant others. SOS(B) is a version which allows the patient to select key individuals to be rated. Each rating has the *actual* level of support received and the *ideal* level of support plus the discrepancy between the two. Ratings are made on a seven-point rating scale where 1 equals 'never' and 7 equals 'always'. The scale takes approximately 10 minutes to complete and raw scores are obtained for each type of support. Raw scores are summed across individuals to give separate measures of emotional support and practical support. Total scores are then divided by the number of individuals rated to give a mean for each type of support in each area. Power *et al.* (1988) reported that the SOS has a satisfactory reliability and validity with test-retest reliability over a six-month period ranging from 0.73 to 0.83 across the four summary support scores.

2.265 Summary of Measures used in the Present Study

The present study therefore employed a combination of the following (Shapiro *et al.* 1994):

1. Objective measures (by the principle investigator)
2. Self-report measures
3. Standardised diagnostic and symptomatic measures
4. Measures as specific as possible to the treatment being evaluated

During treatment, individual targets were assessed using the following:

1. Beck Depression Inventory II (Beck, 1996).
2. Diary to assess any external contributors to differences (Appendix 9.0).

For the Treatment group, immediately post session, the following questionnaires were completed by the therapist (Rounsaville *et al.* 1986) for all patients.

1. Checklist and Rating Form: either *initial sessions* or *termination* (Appendix 10.0).
2. Therapist Strategy Form and Focus Rating Form (Appendix 10.1).
3. Process Rating Form (Appendix 10.2).
4. Overall Therapy Rating Form (Appendix 10.3).

Roth and Fonagy (1996) point out that the reduction of outcomes to a series of scores may be unsatisfactory, as it undoubtedly fails to capture the complexity of the therapeutic work. They argue that as the majority of current measures do not capture the subtleties of individual presentations or the significance of particular changes to particular patients that there is merit in the objection. For this reason, the current study includes case material for two patients: IK, for whom the intervention IPT-B was deemed to be 'successful'; LN in which IPT-B was deemed to be 'unsuccessful' according to pre-trial criteria described for success, utilising RHRSD (both versions) and BDI-II as the main outcome measures.

2.27 The Manuals for the Present Study

In an attempt to specify treatment purity (i.e. the extent to which a treatment is homogeneous across sessions, whilst being consistent with a specified model), four manuals were developed according to the suggestions raised by Wilfley *et al.* (1998) and in agreement with Myrna Weissman, as original author of IPT. The manuals, reproduced from the original pilot study, specify ways in which a therapist should behave within a particular treatment mode and in response to particular clinical situations. Three manuals were devised for the current study, each corresponding to a different focus area, as described earlier (Appendix 11.0).

"Manuals should not be cookbooks that stifle spontaneity. On the other hand, they must provide guidelines sufficient that different therapists tend to respond in similar ways to key therapeutic situations. A properly designed manual offers therapists reassurance that the therapy has been carefully thought out and defined, has coherence, and addresses problems that may arise for the patient and therapist. It should contribute to the therapist's confidence in the treatment, which can in turn be imbued to the patient."

Weissman *et al.* (2000) p387

Roth and Fonagy (1996) suggest that a treatment guideline should include patient presentations that may be the 'exception to the rule' but that the advantages for widening a protocol have to be balanced against the possibility that directives are diluted to the point where they become inappropriately broad and flexible. The manuals developed for the

present study provide session-by-session guidelines with added flexibility for formulation within one of four focus areas as described earlier (Kendall, Chu, Gifford, Hayes and Nauta, 1998). According to Chambless and Ollendick (2001), the better manuals are richly elaborated with examples of dialogue illustrating application of the procedures and with descriptions of courses of action to take when problems arise in treatment. The present manuals attempted to take this advice on board and provide examples of dialogue (Appendix 11.0). According to Chambless and Ollendick (2001), treatment manuals are necessary to provide an operational definition of the intervention under study, because very different procedures may fall under the general rubric of, for example, IPT. In terms of generalisable knowledge, which is at the very heart of the present study, Chambless and Ollendick (2001) state that it is meaningless to say that a treatment works without being able to say what the treatment is.

2.28 Therapist Training

According to Margison and McGrath (1989), good design requires therapists to be trained in order to maintain treatment consistency. In the current trial, only one therapist, trained in Interpersonal Psychotherapy for Depression, utilised the manuals as specified. Indeed, the treatment manuals, together with adherence monitoring, improved the interpretation of the results of the current study. Adherence to the model was monitored, both by the present author and by an independent rater (KC), through audiotaped sessions and use of rating forms (Appendices 10.0-10.3).

2.29 Follow-up Data

The success of the intervention, IPT-B, was measured by its ability to improve patient functioning and to maintain that improvement after therapy ended. According to Roth and Fonagy (1996), the length of follow-up required to demonstrate a clinical effect is governed by the natural history of a disorder, which will suggest both the probability of relapse and the usual length of time between episodes. Therapeutic efficacy can only be demonstrated in the context of both factors. However, there is an important consideration to make when deciding how long the follow-up period should be, as the longer a patient is followed up, the more difficult it is to ascribe change to the original treatment. Therefore, whilst the results of very prolonged follow-up may be desirable, they may be difficult to interpret. In the present study, the length of follow-up was dictated according to the strict timetable imposed, and therefore the results reported pertain to the following:

IPT-B Treatment Group:

Time 1:Baseline; Time 2:End-of-Treatment and Time 3:2-month follow-up.

Waiting List Control Group:

Time 1: Baseline; Time 2: 2-months post-baseline and Time 3: 4-months post-baseline. Times of the control group correspond to the timing of reassessment of the treatment group.

2.30 The Issue of Attrition

The present study aimed to report on the basis of an "intention-to-treat" sample, including all participants who entered into the trial, regardless of whether they completed treatment (Chambless and Ollendick, 2001) as well as presenting separate data for those completing all therapy. Outcome data analyses were therefore conducted on two samples of patients:

1. The Intention to Treat sample included all patients who entered treatment and completed baseline assessment and at least 3 sessions of IPT-B.
2. The completer sample included all patients who completed 8 sessions of IPT-B and all assessment sessions.

According to Elkin *et al.* (1989) the **completer** analysis will best reflect treatment effects for those patients who have received a full course of treatment. The results of the Intention to Treat analysis may be considered an estimate of the overall performance of a treatment programme, including its ability to retain patients in treatment. Data on both samples is included to provide the most complete and accurate representation of the findings.

2.31 Clinical and Statistical Significance

In psychotherapeutic trials, it is conventional to report the statistical significance of differences between treatments in terms of a confidence level of $p < 0.05$ or <0.01. However, as Sterne and Smith (2001) state, the null hypothesis may be rejected at relatively high levels of statistical significance without simultaneously demonstrating that the finding is worthy of clinical attention. The demonstration of statistical effects may not be equivalent to a clinically significant therapeutic change and therefore a number of strategies have been used to detect this; Jacobson and Truax (1991) suggest criteria for the evaluation of **clinically significant** changes in psychotherapy. Definition and subsequent application of the criteria for clinically significant change (Jacobson and Truax, 1991) are presented in Chapter 3.0:Results.

2.32 Statistical Power

It is essential in any health outcome research that the study has sufficient power to detect treatment effects (discussed in Chapter 3.0:Results). In order to minimise threat to the external validity of the research the following were adhered to (Dar, Serlin and Omer, 1994):

1. Planned rather than post hoc statistical decisions.
2. Reduced use of multivariate techniques.
3. Avoidance of the use of stepwise statistical procedures.

Power analyses were used prospectively during the design stage to confirm the sample size required (N=25 in each group for a large effect, Clark-Carter, 1997).

2.33 Analysis of Data

Overall statistical analyses were carried out using the Statistical Package for Social Sciences for Windows, Version 10. Variables were compared using ANOVA, T-Tests and Simple Regression for predictor analysis. Reliable clinical change was assessed utilising criteria as defined by Jacobson and Truax (1991) and Warren's criteria for the definition of successful treatment was applied to the severity of depression outcome data. Effect size was used as a measure of improvement and the summary of effects was calculated, in terms of the number needed to treat.

2.34 Economic Evaluation

An economic evaluation was conducted alongside the study in order to examine the cost effectiveness of IPT-B as compared to routine clinical practice (12-20 weeks CBT). This was carried out in accordance with guidelines for health technology assessment, as required by both the National Institute for Clinical Excellence (NICE) and the Health Technology Board for Scotland (HTBS).

A cost effectiveness analysis was carried out from the perspective of the NHSScotland. Conduct of the analysis was according to published guidelines (Drummond, O'Brien, Stoddart and Torrance 1986). The summary measure was cost per successfully treated patient. The outcome measure of successfully treated patient was defined as a patient whose BDI score was ≤9, as used by Elkin *et al.* (1989) in the NIMH Study.

For comparative purposes, an estimate of the relative cost effectiveness of routine clinical practice was made; a prospective study is now indicated following the results of the main study. As with all economic evaluations a number of assumptions were made, thus a

sensitivity analysis was carried out to investigate the impact of the main assumption (number of routine clinical practice CBT sessions is 18) on the cost effectiveness results.

2.35 Collection of Resource Use Data

In order to calculate the costs associated with the two different models of therapy, it is necessary to collect data concerning the use of health care resources in the delivery of these interventions. An attempt was made to collect resource data using patient diaries (Appendix 9.0) however it was found that participants in the study, regardless of group allocation, failed to comply with completing the diary information. Concerns about compliance with paper diaries are widespread and indeed the validity of using this method has recently been called into question (Stone, Shiffman, Schwartz, Broderick and Hufford, 2002).

In economic evaluation, it is good practice to compare the experimental intervention with standard clinical practice; due to the constraints of the study, it was not possible to prospectively collect resource use and outcome data concerning standard clinical practice. Therefore, published data were used to estimate the relative cost effectiveness of CBT (Elkin *et al.* 1989).

The cost calculations were based on Clinical Psychologist-patient contact time for both the study data and the standard clinical practice comparator. It should be noted that the IPT-B sessions were in fact delivered in the present study by a Trainee Clinical Psychologist qualified in IPT. A median number of 18 sessions of CBT were delivered by either a Psychologist or a Psychiatrist in the NIMH study (Elkin *et al.* 1989). Calculations are based on CBT being delivered by a Community Clinical Psychologist, as it is the relevant comparison in the Primary Care setting. The NIMH study reported that 16-20 sessions of CBT were delivered, the effect of this minimum and maximum number of sessions was explored in sensitivity analysis. The comparator intervention of IPT-B was costed at 8 sessions per patient. The net cost per patient contact with a community clinical psychologist (Scottish Health Service Costs, 2001) includes the direct costs of staff time plus allocated costs (such as administration, cleaning, rent, rates etc.).

The other area of resource consumption that may impact on results is the use of antidepressant medication. As information concerning antidepressant useage was not available for the study patients (due to failure to complete resource use diaries) the effect of the most extreme scenario was tested in sensitivity analysis of the base case results. This

involved the addition of antidepressant drug costs to the cost of treating all IPT-B patients as compared to the treatment costs alone for all CBT patients (i.e. assuming that all IPT-B patients were receiving antidepressants whilst none of the CBT patients were). A further assumption that was made was that the cost of Seroxat 20mg daily (British National Formulary 43, 2002) could be used to impute estimated antidepressant drug costs for all relevant patients.

CHAPTER 3.0

RESULTS

CHAPTER 3.0: RESULTS

3.0 PROCESS OF DATA ANALYSIS

The process of data analysis was carried out and reported in the following phases:

1. Description of the samples (intention-to-treat and completer)
2. Exploratory data analysis prior to statistical analysis
3. Confirmatory statistical outcome analyses related to the main hypotheses in two stages as these relate to the overarching aims of IPT-B: (1) to reduce the symptoms of depression and (2) to improve the quality of interpersonal relationships

(1) SEVERITY OF DEPRESSION

- Primary analyses related to main hypotheses 1 and 3(a)

  Mixed Factorial Design Repeated Measures ANOVA
- Effect size as a measure of improvement: samples stratified for severity
- Clinical significance

  Jacobson's Reliable Change Index (Jacobson and Truax, 1991)
- Overall impression of improvement

  Warren (1994)
- Secondary analyses

  Simple Regression for Predictor Analyses

(2) QUALITY OF INTERPERSONAL RELATIONSHIPS

- Primary analyses related to main hypotheses 2 and 3(b)

  Mixed Factorial Design Repeated Measures ANOVA
- Secondary Analyses

  Mixed Factorial Design Repeated Measures ANOVA

The remaining section of this chapter present results for the economic evaluation of IPT-B as compared to an *estimated* CBT.

3.1 DESCRIPTION OF THE SAMPLES

3.11 Patient Characteristics

As discussed earlier, the present study aimed to report on the basis of an 'intention-to-treat' sample, including all participants who entered into the trial, regardless of whether they completed treatment (Chambless and Ollendick, 2001) as well as presenting separate data for those completing all therapy. Outcome data analyses were therefore conducted on two samples of patients: (1) The intention-to-treat sample included all patients who entered treatment and completed at least 3 sessions of IPT-B. (2) The completer sample included all patients who completed 8 sessions of IPT-B.

According to Elkin *et al.* (1989) the **completer** analysis will best reflect treatment effects for those patients who have received a full course of treatment. The results of the intention-to-treat analysis may be considered an estimate of the overall performance of a treatment programme, including its ability to retain patients in treatment. Unless otherwise stated, data on both samples is provided to give the most complete and accurate representation of the findings.

A total of 81 patients were referred to the study, 58 (71.6 percent of total referred) of whom were fully assessed using the battery of questionnaires and Structured Clinical Interview. Twenty three (28.4 percent) patients were offered at least 2 assessment appointments and failed to attend. Nine (11.1 percent) patients were referred who did not reach inclusion criteria or were inappropriate. Table 5.0 describes the two samples of patients considered for statistical analyses. The total number of patients entered into the study following full assessment was 49 (60.5 percent of original number referred to the study). Total numbers of participants are described in Table 6.0.

Sample	Total Number (control)	Mean Age	Marital Status (percent)					Gender (male)
			M	W	D	Se	Si	
Treatment: ***Completer***	14 (16)	35.76	63.3	2	10.2	4.1	20.4	36.7 percent
Treatment: ***Intent to Treat***	26 (23)	35.73	61	3.8	11.5	7.7	15.4	42.2 percent

M= married/cohabiting; W= widowed; D= Divorced; Se= Separated; Si = Single

Table 5.0: Patient Characteristics of Two Sample Populations

Total Number of participants = 49	Number completed B/L Assessment	Number completed all IPT-B sessions	Number completed FU 1 (end-of-treatment)	Number completed FU 2 (2 month follow up)
IPT - B	26	22	21	21
Waiting List Control	23	N/A	20	19

Table 6.0: Total Participant Numbers

3.12 Early Terminator Group

Because differential dropout can introduce bias in the results and affect interpretation of findings, comparisons of those patients who completed treatment with those who did not on the major demographic and clinical variables obtained before treatment were conducted. No significant differences were found between the early terminator group and the completer sample on any demographic or baseline major outcome measure (BDI-II; RHRSD-CV or RHRSD-PI). Compared to the completer sample, the early terminators were younger (mean age 29) but there were no significant differences found in age between the two groups ($t_{(24)} = 1.21$, n.s. $p=0.24$).[5]

[5] The lack of statistical difference between the early terminator group and the completer group may have been due to a very small number of early terminators. Effect size was found to be 0.64. In order to achieve power of 0.8, 45 participants *in each group* would be required to detect a significant difference with the moderate effect size obtained (Clark-Carter, 1997).

3.2 EXPLORATORY DATA ANALYSIS PRIOR TO STATISTICAL ANALYSIS

3.21 Statistical Power, Effect Size and Significance Level

Statistical power, defined as the probability of *avoiding* a Type II error (Power = 1-ß) was set at 0.8. Clark-Carter (1997) argues that this is a reasonable level of power to aim for i.e. the probability of making a Type II error (ß) is 1-power = 0.2. Power analyses were used prospectively during the design stage for ANOVA, to confirm the sample size required (n=25 in each group for a large effect). The effect size, independent of sample size, is stated for each result reported, to allow for future comparisons of the data. H_0 was rejected if the p-value was less than a 0.05.

Prior to conducting any statistical test, an appropriate exploration of the data set was undertaken in order to ascertain the suitability for the specified test. As the performance of a statistical test presupposes that certain assumptions about the data are correct, the assumptions underlying the model of each test conducted were examined and adhered to.

3.22 Initial Analyses Prior to the Principal Analyses

A one way ANOVA revealed no significant differences between the treatment group and the control group at baseline for the major outcome measures, for either of the sample populations: BDI-II: $F_{(1,47)}=1.43$; n.s. $p=0.24$; Eta squard=0.3; RHRSD-CV: $F_{(1,47)}=0.06$; n.s. $p=0.81$; Eta squared=0.07 and RHRSD-PI: $F_{(1,47)}=0.004$; n.s. $p=0.95$; Eta squared=0.02.

3.3 CONFIRMATORY STATISTICAL OUTCOME ANALYSES

(1) SEVERITY OF DEPRESSION

Primary severity of depression outcome measures for both samples of patients include:

(1) BDI-II

(2) RHRSD-CV

(3) RHRSD-PI

Results are described according to the above outcome measures. Table 7.0 presents means and SDs for the three outcome measures, in each of the two samples.

	TREATMENT		CONTROL	
	N	Mean (SD)	N	Mean (SD)
INTENTION TO TREAT SAMPLE				
BDI-II				
Baseline	26	27.73 (11.97)	23	31.70 (11.14)
End of Treatment	26	15.12 (11.87)	23	24.22 (12.09)
2 Month Follow up	26	13.04 (11.23)	23	23.65 (13.42)
Hamilton Clinician Version				
Baseline	26	17.88 (6.64)	23	17.43 (6.54)
End of Treatment	26	9.77 (6.85)	23	14.65 (9.15)
2 Month Follow up	26	9.04 (6.59)	23	14.30 (9.04)
Hamilton Patient Version				
Baseline	26	22.65 (8.02)	23	22.52 (6.85)
End of Treatment	26	15.69 (9.75)	23	19.83 (9.89)
2 Month Follow up	26	13.54 (10.39)	23	18.65 (11.38)
COMPLETER SAMPLE				
BDI-II				
Baseline	14	26.93 (13.10)	16	33.44 (11.53)
End of Treatment	14	14.71 (13.48)	16	24.63 (11.93)
2 Month Follow up	14	10.86 (11.93)	16	23.81 (13.86)
Hamilton Clinician Version				
Baseline	14	18.29 (7.18)	16	18.56 (6.24)
End of Treatment	14	7.36 (6.37)	16	15.50 (9.45)
2 Month Follow up	14	6.00 (5.10)	16	15.00 (9.34)
Hamilton Patient Version				
Baseline	14	22.21 (8.76)	16	23.31 (6.94)
End of Treatment	14	12.29 (8.86)	16	20.75 (9.42)
2 Month Follow up	14	8.29 (8.11)	16	19.06 (11.73)

Table 7.0: Mean Baseline, End of Treatment and 2-month Follow up Scores for the three Primary Outcome Measures

3.31 Primary Analyses Related to Main Hypotheses 1 and 3(a)

2x(3) Mixed Factorial Design Repeated Measures ANOVA

For all 2x(3) Mixed Factorial Design Repeated Measures ANOVAs described below, any reported unplanned pairwise multiple comparisons (which followed the significant interaction) employed the Bonferroni method[6] with a significance level set at 0.02. For all analyses: Time 1=baseline; Time 2=end-of-treatment; Time 3=2-month follow up.

The following analyses relate to Research Hypotheses 1 and 3(a) as follows:

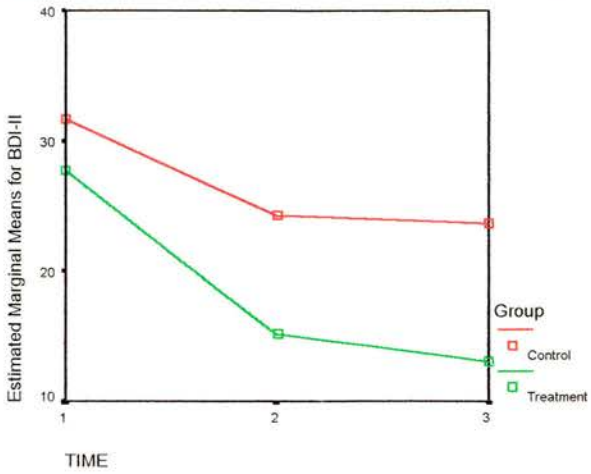
- **Research Hypothesis 1:** The adapted version of IPT to IPT-B is effective in reducing the symptoms of depression when compared to waiting list control.

- **Research Hypothesis 3(a)**: The adapted version of IPT to IPT-B is effective over time in terms of reducing symptoms of depression when compared to waiting list control.

3.311 Outcome Measure 1: BDI-II with Intention-to-Treat Sample

The main effect of time was significant F(2,94)=40.23; $p<0.01$; Eta squared=0.5 and there was clearly a significant difference in performance between the two groups of patients F(1,47)=6.80; $p<0.01$; Eta squared=0.2. The interaction *Group x Time* was also significant F(2,94)=3.161; $p<0.05$; Eta squared=0.1. Graph 1.0 shows that although both groups report reduced symptoms of depression over time, the difference between Time 1 and 3 for the treatment group was greater t(25)=5.94; $p<0.01$; d=1.3; than it was for the control group t(15)=3.08; $p<0.01$; d=4.97.

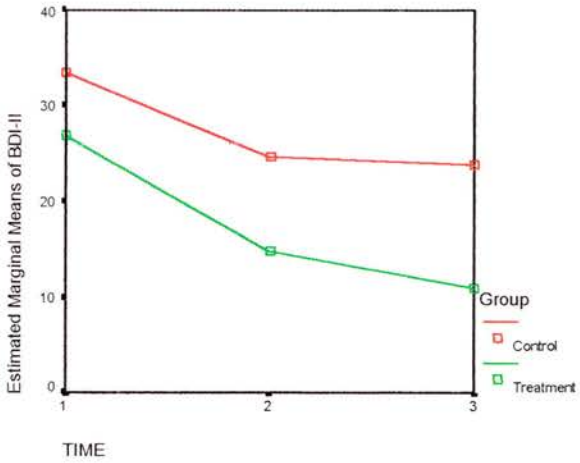
[6] The Bonferroni method was used to adjust the significance level by dividing the per family significance level of 0.05 by 3 (3 possible comparisons, the Bonferroni corrected T Tests are required to show significance beyond the 0.02 level). This more stringent criterion helps reduce the risk of Type I errors associated with multiple comparisons.



Graph 1.0: Time of assessment (1=baseline; 2=end; 3=follow up) of BDI-II across two groups of patients within the Intention-to-Treat Sample

3.312 Outcome Measure 1: BDI-II with Completer Sample

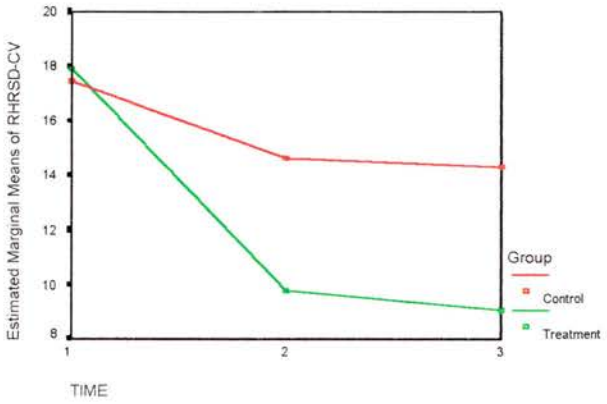
As for the previous sample, the main effect of time was significant F(2,56)=29.64; $p<0.01$; Eta squared=0.5 and there was a significant difference in performance between the two groups of patients F(1,28)=3.56; $p<0.05$; Eta squared=0.2. The interaction *Group x Time* for the Completer sample, however was **not** significant F(2,56)=1.64; n.s. $p=0.20$; Eta squared=0.05. Graph 2.0 shows that both groups report reduced symptoms of depression over time but the treatment group continue to report a decrease in depressive symptoms (from Time 2 to Time 3 t(13)=2.28; n.s; $p=0.04$; d=0.3, whereas the control group do not t(15)=0.57; n.s. $p=0.57$; d=0.07).



Graph 2.0: Time of assessment (1=baseline; 2=end; 3=follow up) of BDI-II across two groups of patients within the Completer Sample

3.313 Outcome Measure 2: RHRSD-CV with Intention-to-Treat Sample

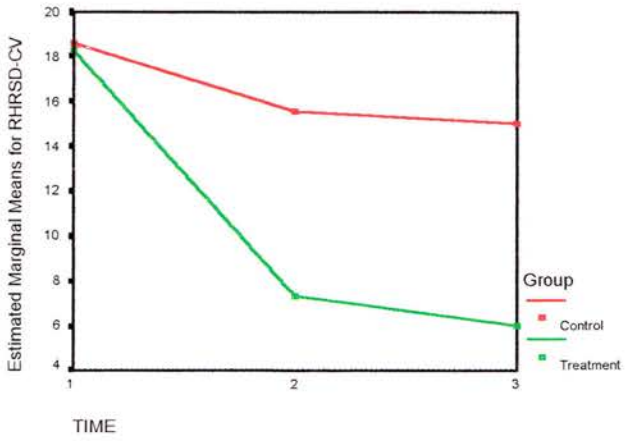
The main effect of time was significant F(2,94)=26.33; $p<0.01$; Eta squared=0.4 but there was not a significant difference in performance between the two groups of patients F(1,47)=2.98; n.s. $p=0.91$; Eta squared=0.6. The interaction *Group x Time* is significant F(2,94)=6.12; $p<0.01$; Eta squared=0.1. Graph 3.0 shows that although both groups report reduced symptoms of depression over time, it is clear that a similar result as for the BDI-II is obtained, in that the difference between Time 1 and 3 for the treatment group t(25)=5.34; $p<0.01$; d=1.3, is greater than it is for the control group t(22)=2.14; n.s. $p=0.04$; d=0.5.



Graph 3.0: Time of assessment (1=baseline; 2=end; 3=follow up) of RHRSD-CV across two groups of patients within the Intention-to-Treat Sample

3.314 Outcome Measure 2: RHRSD-CV with Completer Sample

Examination of the results for the Completer Sample indicate a similar pattern as described above, with a significant Time effect F(2,56)=28.66; $p<0.01$; Eta squared=0.5; a significant

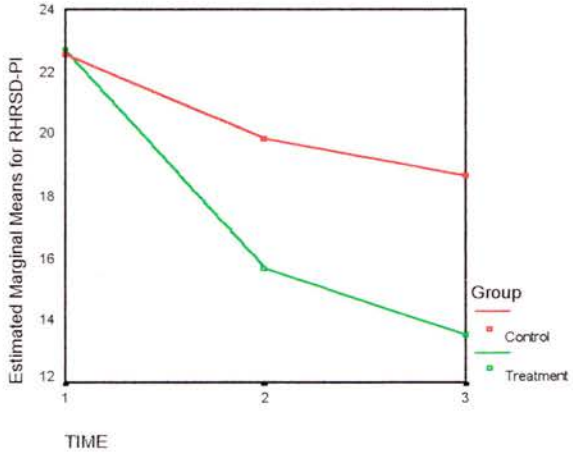


Graph 4.0: Time of assessment (1=baseline; 2=end; 3=follow up) of RHRSD-CV across two groups of patients within the Completer Sample

interaction between Time and Group F(2,56)=8.83; *p<0.01;* Eta squared=0.2 but for this sample a significant difference **between** the groups was obtained F(1,28)=5.76; *p=0.02;* Eta squared=0.2, as shown in Graph 4.0. Although both groups report reduced symptoms of depression over time, the difference between Time 1 and 3 for the treatment group was greater t(13)=6.82; *p<0.01*; d=2.40, than it was for the control group t(15)=1.75; n.s; *p=0.10;* d= 0.6 (Graph 4.0).

3.315 Outcome Measure 3: RHRSD-PI with Intention-to-Treat Sample

The main effect of time was significant F(2,94)=20.63; *p<0.01;* Eta squared=0.3 but there was no significant difference between the groups F(1,47)=1.56; n.s; *p=0.22;* Eta squared=0.03. The interaction *Group x Time,* was significant F(2,94)=3.53; *p=0.03*; Eta squared=0.7. Graph 5.0 shows that although both groups report reduced symptoms of depression over time, it was clear that the difference between Time 1 and 3 for the treatment group was greater t(25)=4.70; *p<0.01*; d=0.9, than it was for the control group t(22)=2.43; n.s; *p=0.02;*d=0.6.

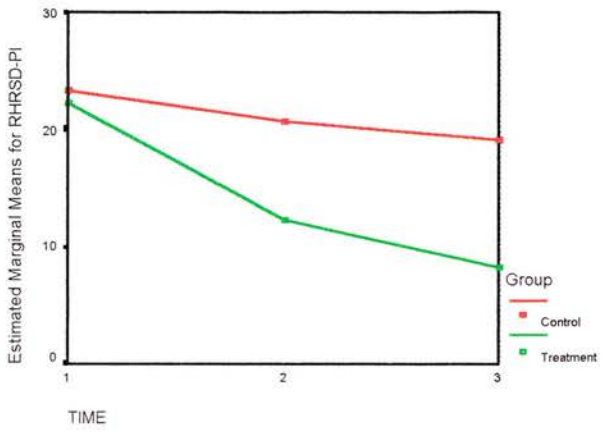


Graph 5.0: Time of assessment (1=baseline; 2=end; 3=follow up) of RHRSD-PI across two groups of patients within the Intention-to-Treat Sample

3.316 Outcome Measure 3: RHRSD-PI with Completer Sample

Examination of the results for the Completer Sample indicate a similar pattern as described above, for the Intention-to-Treat Sample, with a significant time effect F(2,56)=21.90; *p<0.01;* Eta squared=0.4 a significant interaction between Time and Group F(2,56)=6.47; *p<0.01;* Eta squared=0.2 but for this sample, a significant difference **between** the groups was obtained as shown in Graph 6.0, F(1,28)=5.40; *p=0.02;* Eta squared=0.2. Graph 6.0 shows that although both groups report reduced symptoms of depression over time, it is clear

that the difference between Time 1 and 3 for the treatment group was greater t(13)=5.4;$p<0.01$; d=1.6 than it is for the control group t(15)=2.04; n.s; $p=0.06$;d=0.6.



Graph 6.0: Time of assessment (1=baseline; 2=end; 3=follow up) of RHRSD-PI across two groups of patients within the Completer Sample

3.317 Summary of Analysis of Primary Severity of Depression Outcome Measures

The general direction of results was similar in all analyses and for both samples. Over time, both treatment and control groups (in both samples) reported decreased symptoms of depression but the difference between baseline and 2-month-follow up was generally greater in the treatment group than in the control group, indicating a significant improvement in symptoms of depression through IPT-B when compared to waiting list control.

3.4 EFFECT SIZE with SEVERITY OF DEPRESSION

As a measure of improvement (in terms of severity of depressive symptoms) expressed as an **effect size,** for the IPT-B treatment group, depressed patients from both samples, showed a substantial improvement using the major outcome measures of BDI-II, RHRSD-CV and RHRSD-PI. Tables 8.0 and 9.0 show that for both samples, large effect sizes were obtained (Cohen, 1988) all of which increased over time from end-of-treatment to 2-month follow up, demonstrating greater improvement.

Outcome Measure	Pre Therapy Mean	Pre Therapy SD	Post Therapy Mean (end treatment)	Effect Size (Cohen, 1988) μ0-μ1/SD	Post Therapy Mean (2 mo FU)	Effect Size (Cohen, 1988) μ0-μ1/SD
BDI-II	27.73	11.97	15.12	1.05	13.04	1.22
RHRSD – CV	17.88	6.64	9.77	1.22	9.04	1.33
RHRSD – PI	22.65	8.02	15.69	0.87	13.54	1.14

Table 8.0: Effect Sizes for Intention-to-Treat Sample at the End-of-treatment and at Follow Up

Outcome Measure	Pre Therapy Mean	Pre Therapy SD	Post Therapy Mean (end treatment)	Effect Size (Cohen, 1988) μ0-μ1/SD	Post Therapy Mean (? mo FU)	Effect Size (Cohen, 1988) μ0-μ1/SD
BDI-II	26.93	13.10	14.71	0.93	10.86	1.41
RHRSD – CV	18.29	7.18	7.36	1.52	6.00	1.79
RHRSD – PI	22.21	8.76	12.29	1.13	8.29	1.79

Table 9.0: Effect Sizes for Completer Sample at the End-of-treatment and at Follow Up

3.41 Exploratory Analyses Using Initial Severity of Depression and Effect Size

By design, the patient sample included a fairly wide range of depression, however it has previously been suggested that the initial level of severity is associated with outcome of treatment (e.g. Elkin *et al.*1989) and this was indeed found within the present study. The samples therefore were divided into those presenting with less severe symptoms of depression at baseline and those presenting with more severe symptoms. These analyses were considered to be exploratory, as the design did not include stratification on this variable. Severity was defined using the Clinician Rated version of the RHRSD and a score of ≥20. Tables 10.0 and 11.0 show that in both samples, patients presenting with more severe symptoms of depression at baseline demonstrate greater improvement after treatment than

those with less severe symptoms; the improvement increasing with time from end-of-treatment to 2-month follow up.

Outcome Measure	Pre Therapy Mean		Pre Therapy SD		Post Therapy Mean (end)		Effect Size (Cohen, 1988) μ0-μ1/SD		Post Therapy Mean (2 mo FU)		Effect Size (Cohen, 1988) μ0-μ1/SD	
	Intent	*Comp*	*Intent*	*Comp*	*Intent*	*Comp*	*Intent*	*Comp*	*Intent*	*Comp*	*Intent*	*Comp*
BDI-II	33.46	33.46	10.19	10.19	19.15	19.64	1.40	1.36	15.85	14.44	1.73	1.88
RHRSD – CV	23.31	23.31	3.25	3.25	12.00	10.36	**3.48**	**3.98**	10.23	7.78	**4.02**	**4.78**
RHRSD – PI	26.38	26.38	7.72	7.72	17.69	15.00	1.12	1.47	14.54	9.33	1.53	2.21

Table 10.0: Effect Sizes for Patients Presenting with Severe Depression at baseline (RHRSD≥20)
Intent = Intention-to-Treat Sample
Comp = Completer sample

Outcome Measure	Pre Therapy Mean		Pre Therapy SD		Post Therapy Mean (end)		Effect Size (Cohen, 1988) μ0-μ1/SD		Post Therapy Mean (2 mo FU)		Effect Size (Cohen, 1988) μ0-μ1/SD	
	Intent	*Comp*	*Intent*	*Comp*	*Intent*	*Comp*	*Intent*	*Comp*	*Intent*	*Comp*	*Intent*	*Comp*
BDI-II	25.13	25.13	12.37	12.37	11.69	10.83	1.08	1.16	10.94	8.86	1.15	1.32
RHRSD – CV	13.88	13.88	4.81	4.81	9.00	6.42	1.01	1.55	8.94	5.00	1.03	1.85
RHRSD – PI	20.94	20.94	8.93	8.93	15.44	11.50	**0.62**	1.06	14.00	8.29	**0.77**	1.42

Table 11.0: Effect Sizes for Patients Presenting with Less Severe Depression at Baseline (RHRSD<20) *Intent = Intention-to-Treat Sample*
Comp = Completer sample

3.5 CLINICAL SIGNIFICANCE OF RESEARCH FINDINGS

The clinical significance of research findings is an important issue and one that is often neglected (Ogles, Lambert and Sawyer, 1995). The present study therefore sought not only to present statistical significance for group means, but also the variety of individual responses to treatment and the practical meaningfulness of individual change. Jacobson and Truax (1991) have proposed two criteria for assessing clinical change: (1) patients who receive treatment should move from a theoretical dysfunctional population to a functional population as a result of treatment and (2) the change must be reliable. Movement into the functional distribution is determined by establishing a cut-off score beyond which patients are considered to be more similar to the functional group than the dysfunctional group. The criterion chosen to represent clinically significant change was Criterion C:

"The level of functioning subsequent to therapy places that client closer to the mean of the functional population than it does to the mean of the dysfunctional population."

Jacobson and Truax (1991) p13: Criterion C

It is based on the relative likelihood of a particular score ending up in dysfunctional versus functional population distributions. Clinically significant change would be inferred when a post-treatment score falls within the functional population on the variable of interest. When the score satisfies this criterion, it is statistically more likely to be drawn from the functional than from the dysfunctional population.

Reliability is determined by calculating a reliable change index (RCI), which if greater than 1.96, suggests that the pre-to post-treatment change is not a product of random fluctuations in test scores. If the patient meets both criteria, the pre to post treatment change is identified as ***clinically significant*** (Jacobson and Truax, 1991).

The outcome measures selected for evaluating clinical significance in both samples, were the BDI-II, RHRSD-CV and RHRSD-PI. Reliability estimates were obtained from published studies or test manuals (e.g. the BDI-II (Beck, Steer and Brown, 1996)), the Revised Hamilton Rating Scale for Depression (RHRSD-CV and PI; Warren, 1994). Descriptive statistics for a functional population were obtained from normative samples identified in the instruments' manuals. Table 12.0 shows that a substantial number of patients

in the IPT-B treatment group demonstrated reliable change on all three major measures of outcome and when compared to waiting list controls (Appendix 12.0).

MEASURE	IPT-B End-of-treatment *n*(percent)		IPT-B 2-month follow-up *n*(percent)		Waiting List Control Group End *n*(percent)		Waiting List Control 2-month follow-up *n*(percent)	
	Intent	*Comp*	*Intent*	*Comp*	*Intent*	*Comp*	*Intent*	*Comp*
RHRSD-CV								
RCI>1.96	9 (35)	9 (35)	12 (46)	12 (46)	5 (22)	4 (20)	5 (22)	4 (20)
Clinically Significant Change	16 (62)	16 (62)	17 (66)	17 (66)	10 (43)	9 (45)	11 (48)	10 (50)
Reliable Deterioration	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (4)	1 (4)
Initial Score decreased by ≥ 1/3 or <10	15 (58)	15 (58)	17 (65)	17 (65)	8 (35)	8 (35)	9 (39)	9 (39)
RHRSD-PI								
RCI>1.96	10 (38)	10 (38)	13 (50)	13 (50)	4 (17)	3 (15)	6 (26)	5 (25)
Clinically Significant Change	16 (62)	16 (62)	**19 (73)**	**19 (73)**	11 (48)	10 (50)	12 (52)	11 (55)
Reliable Deterioration	1 (4)	1 (4)	0 (0)	0 (0)	1 (4)	1 (4)	1 (4)	1 (4)
Initial Score decreased by ≥ 1/3 or <10	12 (46)	12 (46)	14 (54)	14 (54)	7 (30)	7 (30)	9 (39)	9 (39)
BDI-II								
RCI>1.96	16 (62)	15 (68)	17 (65)	16 (73)	9 (39)	9 (39)	7 (30)	7 (30)
Clinically Significant Change	17(66)	13 (60)	17 (66)	14 (64)	7 (30)	6 (30)	9 (39)	8 (40)
Reliable Deterioration	1 (4)	1 (4)	1 (4)	1 (4)	0 (0)	0 (0)	0 (0)	0 (0)

Table12.0: Evaluation of Clinically Significant Change in Two Sample Populations

Intent = Intention-to-Treat Sample

Comp = Completer Sample

BDI-II = Beck Depression Inventory-II

RHRSD-CV = Revised Hamilton Rating Scale for Depression - Clinician Version

RHRSD-PI = Revised Rating Scale for Depression - Self Rated Problem Inventory.

RCI>1.96 represents the number of individual who reliably improved. Clinically significant change represents clinically significant change using Jacobson's criteria of *"the level of functioning subsequent to therapy places that client closer to the mean of the functional population than it does to the mean of the dysfunctional population"* (Jacobson and Truax, 1991) using

$$C = \frac{SoM1 + S1Mo}{So + S1}$$

Deterioration represents the number of patients who reliably deteriorated.

Initial Score decreased by ≥ 1/3 or – <10 at post treatment represent criteria according to Warren (1994) to define successful treatment on the RHRSD

An interesting observation from the data presented in Table 12.0 is that the greatest change was demonstrated through self-report on the RHRSD-PI whereby 73 percent of patients made what is considered as a **clinically significant** change by 2-month follow up. In the IPT-B treatment group, all initial changes observed at the end-of-treatment were maintained through to 2-month follow up in both treatment group and waiting list control group.

3.6 OVERALL IMPRESSION OF IMPROVEMENT: WARREN (1994)

Warren (1994) suggests that one method of defining successful treatment is through the observation that at follow up, the RHRSD score will have decreased by 1/3 in its initial severity or equal to less than 10 at post treatment (0-6 months). Application of Warren's criteria to the results of the full study reveals that at the end-of-treatment, 58 percent of the IPT-B treatment group reached criteria for success on the RHRSD Clinician Rated version whilst 65 percent reached criteria for success by 2 month follow-up. This result clearly demonstrates patient improvement status over time, especially when compared to only 39 percent of the waiting list control group reaching criteria for success by 2 month follow-up.

For the Self-Rated version of the same scale, 54 percent of the IPT-B treatment group reached Warren's (1994) criteria for success by 2 month follow-up, compared to only 39 percent of the waiting list control group. By Warren's (1994) criteria, IPT-B can certainly be defined as a successful treatment for the majority of patients presenting to Primary Care in the present study and certainly more successful in terms of reduction of symptoms of depression than the waiting list control Group.

3.61 Summary of Effects of IPT-B compared to Waiting List Control

In order to examine the effects of IPT-B in terms of the likely benefit that an individual patient can expect, the relative risk reduction, the absolute risk reduction, and the number needed to treat were calculated as detailed in Table 13.0 (Greenhalgh, 1997):

CALCULATING THE "BOTTOM LINE" EFFECTS ON AN INTERVENTION						
	Outcome Event = Clinically Significant Change					
	BDI-II	RHRSD-CV	BDI-II	RHRSD-CV	BDI-II	RHRSD-CV
Group	**Yes**		**No**		**Total**	
Control Group	a. 9	11	b. 14	12	a.+b=23	a.+b=23
Experimental Group	c. 17	17	d. 9	9	c.+d=26	c.+d=26

Table 13.0: The "Bottom Line" Effects on IPT-B

Control event rate (CER)=risk of outcome event in control group=a/(a+b)
Experimental event rate (EER)=risk of outcome event in experimental group=c/(c+d)
Relative risk reduction (RRR)=(CER-EER)/CER
Absolute risk reduction (ARR)=CER-EER
Number needed to treat (NNT)=1/ARR=1/(CER-EER)

Results demonstrated that when clinically significant change (Jacobson and Truax, 1991) on the BDI-II was used as outcome event, the number needed to treat (NNT) was 0.74. This result shows that **less than one patient** is needed to treat with IPT-B, to achieve one successful outcome. The same result is achieved when using the clinician rated scale of the RHRSD, i.e. NNT = 0.83, therefore less than one patient is NNT with IPT-B to achieve one successful outcome.

3.7 SECONDARY ANALYSES ASSOCIATED WITH SEVERITY OF DEPRESSION

3.71 Can One Predict Reliable Change?

In order to explore whether any of the patient characteristics within the present study could predict reliable change, in terms of severity of depressive symptoms following therapy, scatterplots were examined for linear relationships. These analyses must be considered exploratory, since the design did not include prediction of patient characteristics related to outcome. The only patient characteristic to demonstrate a linear relationship with outcome, was that of initial severity of depression (r=0.58; n=26; $p<0.01$) which has previously been reported in the literature as being of importance in terms of prediction of outcome, (e.g. Elkin *et al.,* 1989; Simons, Lustman and Wetzel, 1985; Woody, McLellan, and Luborsky, 1984).

Simple 2-variable regressions were carried out to determine whether initial severity of depression could predict Reliable Change following therapy, as measured by Reliable Change Index (Jacobson and Truax, 1991). As illustrated in Figure 2.0, a significant model emerged ($F_{1,24}$= 12.370, p =0.002). Adjusted R square = 0.313. Baseline BDI-II is therefore a significant predictor of Reliable Change (Beta = 0.583; p=0.02). Therefore the regression equation is Y' = 0.142X-0.74 (where Y =predicted reliable change and X = baseline BDI-II score).

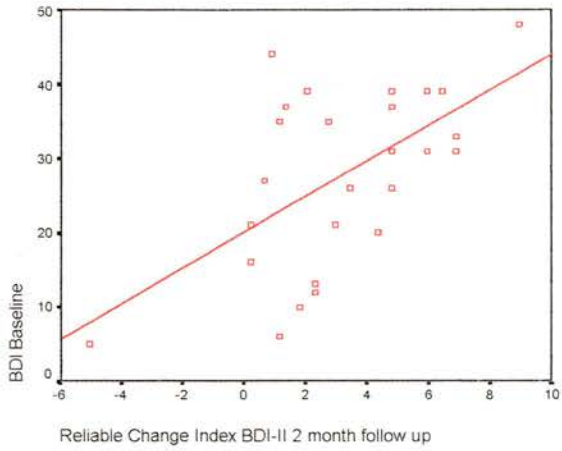


Figure 2.0: Scatterplot of BDI-II Baseline against Reliable Change Index of BDI-II

A further Regression was carried out using RHRSD-Clinician Version as the outcome measure to determine whether baseline RHRSD could reliably predict change, as illustrated in Figure 3.0., a significant model emerged ($F_{1,24} = 10.17$, $p = 0.004$). Adjusted R square = 0.268. Therefore, the only significant predictor of Reliable Change following therapy, using RHRSD as the outcome measure, was RHRSD taken at baseline (Beta = 0.503; $p = 0.005$). The regression equation is Y' = 0.149X-0.70, where X=baseline RHRSD Score.

Results for two major outcome measures (BDI-II and RHRSD) demonstrate that the only predictors of Reliable Change (after IPT-B) were their respective baseline measures.

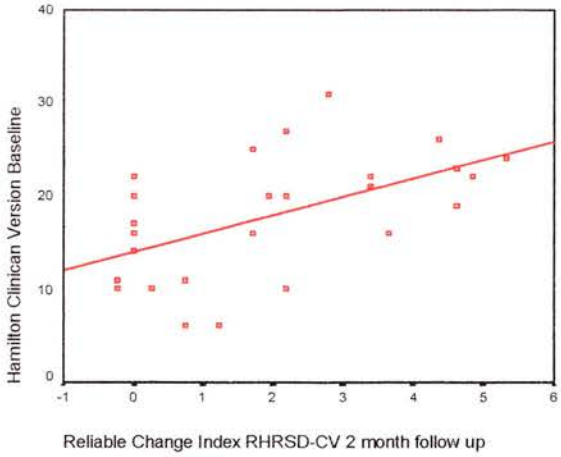


Figure 3.0: Scatterplot of RHRSD-CV Baseline against Reliable Change Index of RHRSD-CV

Examination of Figures 2.0 and 3.0 demonstrate that as baseline severity increases, so too does the change over therapy, as measured by the Reliable Change Index (Jacobson and Truax, 1991). Therefore, those who are more severely depressed at baseline can expect most change using self-report or clinician rated scales.

3.72 Can Severity of Depression at Baseline Predict Severity of Outcome?

The same process, as described above, was carried out for severity of outcome using two major outcome measures (1)BDI-II as the self-report measure (as illustrated in Figure 4.0) and (2)RHRSD as the Clinician Rated outcome measure. Final 2-month follow-up scores were used as the outcome and initial severity of depression was used as the predictor variable.

3.721 Can Self-Report Predict Severity of Outcome?

The model which emerged was significant ($F_{1,24}$=4.898, p=0.037). Adjusted R square = 0.135. Self-Report at baseline was a significant predictor of severity of outcome. Beta = 0.412; p=0.037). The regression equation is: Y'=0.386X+2.32.

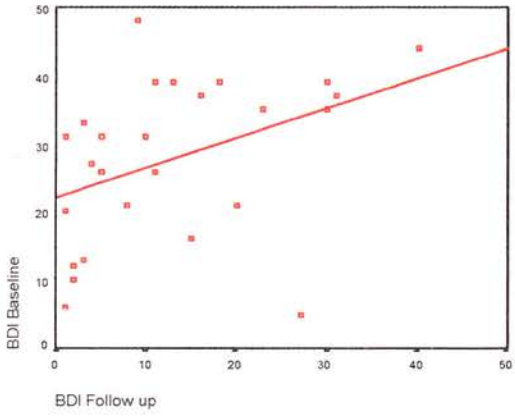


Figure 4.0: Scatterplot of BDI-II Baseline against BDI-II Follow up

3.722 Can Clinician Rating Predict Severity of Outcome?

For the clinician-rated outcome measure, RHRSD-CV, the model which emerged was not significant ($F_{1,24}$=0.831, *n.s.* p=*0.371*). Baseline RHRSD-CV did not significantly predict severity of outcome as measured by the same method: Beta = 0.183; p=0.371. The model emerged as **not significant** which may have been due to the fact that the test had insufficient power to achieve statistical significance. Retrospective sample size was calculated which

would be necessary, for the given effect size, to achieve power of 0.8. The number of participants was 26, after analysis using simple regression with 1 predictor variable, effect size was found to be $R^2 = 0.03$. Using tables as supplied by Clark-Carter (1997), the test, therefore, only had an estimated power of 0.152 (which is very small according to Cohen, 1988). In order to achieve the desired power of 0.8, approximately 390 participants would be required. This large sample size underlines the finding that Clinician Rating on the RHRSD cannot predict the severity of outcome and therefore should not be used for this purpose.

Therefore, one can predict **reliable change** from a measure of baseline severity of depression but only the BDI-II can predict **severity of outcome** from its baseline measure.

3.8 CONFIRMATORY STATISTICAL OUTCOME ANALYSES

(2) QUALITY OF INTERPERSONAL RELATIONSHIPS

Primary quality of interpersonal relationships outcome measures for both samples of patients include:

(1) SOS (emotional and practical support)
(2) WHOQOL-Bref (social relationships domain)

Results are described according to the above outcome measures. Table 14.0 presents means and SDs for the outcome measure SOS, in each of the two samples.

	TREATMENT		CONTROL	
	N	Mean (SD)	N	Mean (SD)
INTENTION TO TREAT SAMPLE				
SOS: Discrepancy Emotional				
Baseline	26	2.96 (2.08)	23	2.66 (2.06)
End of Treatment	26	2.49 (2.15)	23	2.39 (1.75)
2 Month Follow up	26	2.15 (2.04)	23	2.28 (1.71)
SOS: Discrepancy Practical				
Baseline	26	2.68 (2.19)	23	2.17 (1.47)
End of Treatment	26	2.41 (2.42)	23	1.65 (1.26)
2 Month Follow up	26	2.21 (2.17)	23	1.42 (1.07)
COMPLETER SAMPLE				
SOS: Discrepancy Emotional				
Baseline	14	2.48 (2.12)	15	2.61 (2.10)
End of Treatment	14	1.82 (1.99)	15	2.43 (1.60)
2 Month Follow up	14	1.14 (1.37)	15	2.23 (1.57)
SOS: Discrepancy Practical				
Baseline	14	2.05 (1.41)	15	2.52 (1.41)
End of Treatment	14	1.89 (2.20)	15	1.85 (1.21)
2 Month Follow up	14	1.46 (1.34)	15	1.50 (0.91)

Table 14.0: Means and SDs for the Outcome Measures SOS in each of the Two Samples.

3.81 Primary Analyses Related to Main Hypothesis 2 and 3(b)

2x(3) Mixed Factorial Design Repeated Measures ANOVA

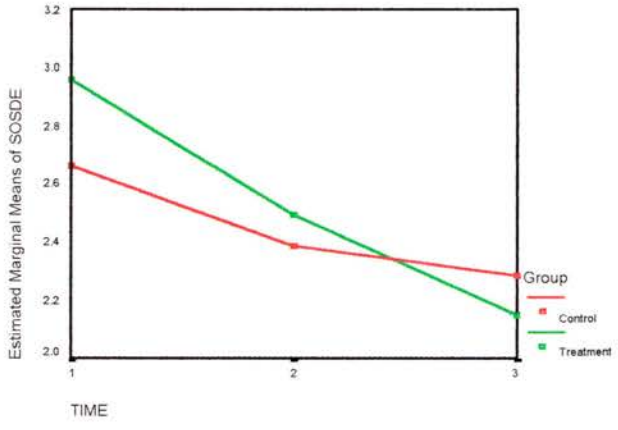
The following analyses relate to Research Hypotheses 2 and 3(b) as follows:

- **Research Hypothesis 2:** The adapted version of IPT to IPT-B is effective in improving the quality of interpersonal relationships when compared to waiting list control

- **Research Hypothesis 3(b)**: The adapted version of IPT to IPT-B is effective over time in terms of improving the quality of interpersonal relationships when compared to waiting list control.

3.811 Outcome Measure 4: SOS: Emotional Support with Intention-to-Treat Sample

When the *discrepancy* between the **ideal** emotional support and the **actual** emotional support was examined, the main effect of time was significant F(2,94)=4.07; *p0.02;* Eta squared=0.1



Graph 7.0: Time of assessment (1=baseline; 2=end; 3=follow up) of SOSDE across two groups of patients within the Intention-to-Treat Sample

Graph 7.0 clearly shows that within the treatment group, the discrepancy between the ideal and actual emotional support decreases over time from baseline to 2-month follow up, confirmed through employment of the Bonferroni post-hoc test t(25)=2.37; n.s; *p=0.02,* d=0.4. No significant difference was observed for the control group over the same time period, t(22)=1.02, n.s; *p=0.32*; d=0.2. No significant differences emerged between the

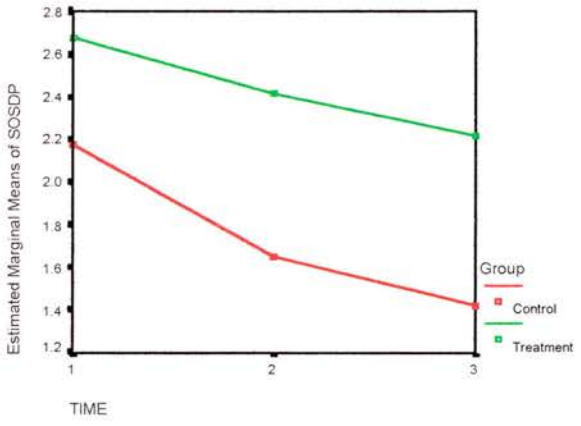
groups F(1,47)=0.03, n.s; *p=0.86;* Eta squared=0.001 or as an interaction between Time and Group F(2,94)=0.53, n.s; *p=0.59;* Eta squared= 0.01.

3.812 Outcome Measure 4: Significant Others Scale: Emotional Support with Completer Sample

The same pattern of results was obtained for the Completer sample as described for the previous Intention-to-Treat sample. The main effect of time was significant F(2,54)=3.83; *p=0.03;* Eta squared=0.1. No significant differences emerged between the groups F(1,27)=1.16, n.s; *p=0.29;* Eta squared=0.04 or as an interaction between Time and Group F(2,54)=1.20, n.s; *p=0.31*; Eta squared=0.04.

3.813 Outcome Measure 4: Significant Others Scale: Practical Support with Intention-to-Treat Sample

A similar pattern of results as those obtained for emotional support was obtained for practical support and within both samples. The main effect of time was significant F(2,94)=5.42: *p<0.01;* Eta squared=0.1. No significant differences emerged between the groups F(1,47)=1.98, n.s; *p=0.17;* Eta squared=0.04 or as an interaction between Time and Group F(2,94)=0.34; n.s; *p=0.71;* Eta squared=0.01, as shown in Graph 8.0.



Graph 8.0: Time of assessment (1=baseline; 2=end; 3=follow up) of SOSDP across two groups of patients within the Intention-to-Treat Sample

3.814 Outcome Measure 4: Significant Others Scale: Practical Support with Completer Sample

The main effect of time was significant F(2,54)=4.54: $p<0.01$; Eta squared=0.1. No significant differences emerged between the groups F(1,27)=0.12, n.s; $p=0.75$; Eta squared<0.01, or as an interaction between Time and Group F(2,54)=0.53; n.s; $p=0.59$; Eta squared=0.02.

3.815 Outcome Measure 5: World Health Organisation Quality of Life Scale - Bref Version

The WHOQOL-Bref measures the perceived quality of life within four domains: Psychological, Social Relationships, Physical Capacity and Environmental. The results are reported initially for the **Social Domain,** as they relate to the main hypotheses (2) and 3(b). Results for the remaining 3 domains are reported as secondary analyses. Table 15.0 presents means and SDs for the outcome measure WHOQOL-Bref for each of the four domains, in each of the two samples.

WHOQOL:BREF	TREATMENT		CONTROL	
	N	Mean (SD)	N	Mean (SD)
INTENTION TO TREAT SAMPLE				
Psychological				
Baseline	26	14.54 (4.79)	23	13.13 (3.88)
End of Treatment	26	17.62 (4.89)	23	15.13 (4.45)
2 Month Follow up	26	18.42 (4.99)	23	15.57 (4.14)
Social Relationships				
Baseline	26	8.38 (2.42)	23	8.17 (2.95)
End of Treatment	26	9.58 (2.34)	23	9.00 (3.00)
2 Month Follow up	26	9.62 (2.86)	23	9.13 (2.85)
Environmental				
Baseline	26	27.81 (5.00)	23	26.26 (6.72)
End of Treatment	26	29.50 (5.37)	23	26.61 (6.67)
2 Month Follow up	26	29.62 (5.08)	23	26.57 (6.32)
Physical Capacity				
Baseline	26	22.77 (4.54)	23	18.78 (5.99)
End of Treatment	26	25.46 (4.18)	23	20.74 (5.86)
2 Month Follow up	26	25.73 (3.90)	23	21.17 (5.65)
COMPLETER SAMPLE				
Psychological				
Baseline	14	14.79 (4.49)	15	13.13 (2.61)
End of Treatment	14	19.07 (4.53)	15	14.80 (3.49)
2 Month Follow up	14	20.57 (4.07)	15	15.47 (2.88)
Social Relationships				
Baseline	14	8.71 (2.95)	15	7.80 (2.86)
End of Treatment	14	10.29 (2.52)	15	8.47 (2.95)
2 Month Follow up	14	10.36 (3.39)	15	8.67 (2.74)
Environmental				
Baseline	14	29.64 (4.68)	15	25.93 (6.42)
End of Treatment	14	31.93 (4.81)	15	26.07 (6.02)
2 Month Follow up	14	32.14 (4.04)	15	26.00 (5.39)
Physical Capacity				
Baseline	14	22.31 (3.95)	15	18.53 (5.37)
End of Treatment	14	26.46 (3.55)	15	20.93 (6.51)
2 Month Follow up	14	27.00 (2.58)	15	21.60 (6.19)

Table 15.0: Means and SDs for the WHOQOL Outcome Measures in each of the Two Samples.

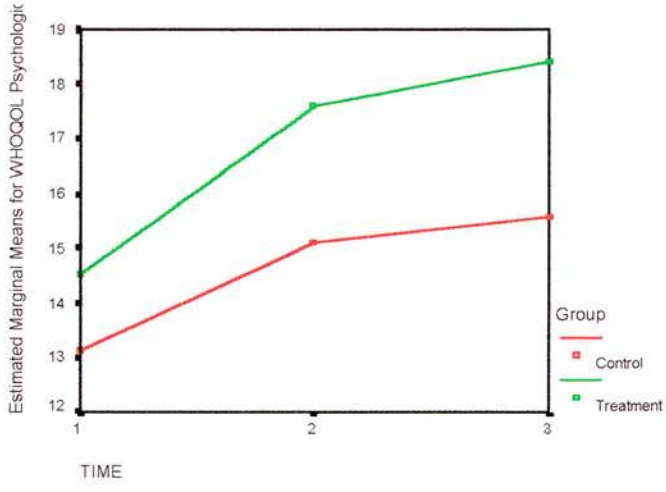
3.816 Domain 1: Social Relationships

Intention-to-Treat and Completer Samples

For both the Intention-to-Treat and the Completer samples, only the main effect of time was significant F(2,94)=10.35; $p<0.01$; Eta squared=0.2 and F(2,52)=7.54; $p<0.01$; Eta squared=0.2 respectively.

3.817 ***Secondary Analysis*** *for Domain 2 -Psychological: Intention-to-Treat Sample*

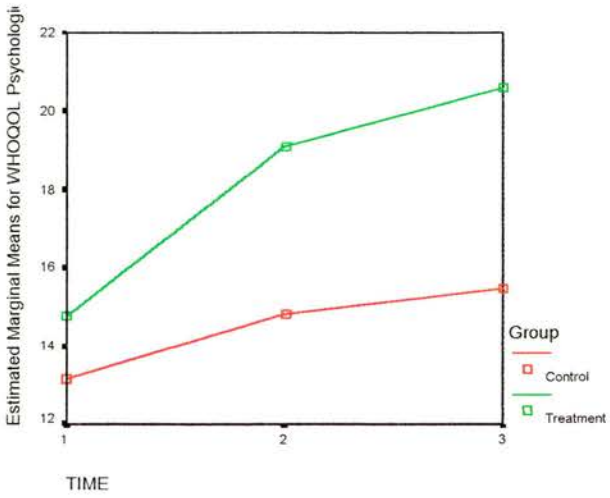
The main effect of time was significant F(2,94)=19.80; $p<0.01$; Eta squared=0.3 and there was also a significant difference between the two groups F(1,47)=3.80; $p<0.05$; Eta squared=0.1. The interaction *Group x Time*, however was **not** significant F(2,94)=1.00; n.s; $p=0.37$; Eta squared=0.02. Graph 9.0 shows that both groups report improved quality of life within the Psychological domain and post hoc analyses confirmed a significant difference between Time 1 and 3 for the treatment group t(25)=3.88; $p<0.01$, d=0.8 and significant difference between Time 1 and 3 for the control group t(22)=3.49; $p<0.01$; d=0.6.



Graph 9.0: Time of assessment (1=baseline; 2=end; 3=follow up) of WHOQOL across two groups of patients within the Intention-to-Treat Sample: Psychological Domain

3.818 ***Secondary Analysis*** *for Domain 2 -Psychological: Completer Sample*

The main effect of time was significant F(2,54)=24.14; $p<0.01$; Eta squared=0.5. The interaction *Group x Time* was also significant F(2,54)=4.43; $p=0.01$; Eta squared=0.1 and there was a clear difference in performance between the two groups of patients F(1,27)=9.43; $p<0.01$; Eta squared=0.3, as can be observed from Graph 10.0.



Graph 10.0: Time of assessment (1=baseline; 2=end; 3=follow up) of WHOQOL across two groups of patients within the Completer Sample: Psychological Domain

Although both groups report increased perceived quality of life within the Psychological Domain over time, the difference between Time 1 and 3 for the treatment group was greater t(13)=4.75; $p<0.01$; d=1.4 than it was for the control group t(14)=4.32; $p<0.01$; d=0.9.

3.819 ***Secondary Analysis*** *for Domain 3: Environment*

Intention-to-Treat and Completer Samples

For the Intention-to-Treat sample only the main effect of time was significant F(2,94)=3.95; $p=0.02$; Eta squared=0.8. For the Completer sample, the main effect of time was significant F(2,54)=4.44; $p=0.02$; Eta squared=0.1. The interaction *Group x Time* was also significant F(2,54)=3.79; $p=0.03$; Eta squared=0.1 and there was a clear difference in performance between the two groups of patients F(1,27)=7.65; $p=0.01$; Eta squared=0.2.

3.820 ***Secondary Analysis*** *for Domain 4:Physical Capacity*

Intention-to-Treat and Completer Samples

For both the Intention-to-Treat and the Completer samples, the main effect of time was significant F(2,94)=13.60; $p<0.01$; Eta squared=0.2, and F(2,52)=17.51; $p<0.01$; Eta squared=0.4, respectively. A significant difference in performance between the two groups was also observed for the Intention-to-Treat and Completer samples F(1,47)=11.74; $p<0.01$; Eta squared=0.2 and F(1,26)=8.21; $p<0.01$; Eta squared=0.2 respectively.

3.9 ECONOMIC EVALUATION

3.91 Clinical Psychologist Cost

The cost per patient contact with a Clinical Psychologist is reported to be £77 (Scottish Health Service Costs, 2001). A course of 18 sessions of Clinical Psychologist time, for example with CBT, is calculated to cost £1386 whereas a course of 8 sessions, for example with IPT-B, is calculated to cost £616.

3.92 Antidepressant drug cost

The cost per month for antidepressant useage can be calculated from the BNF (BNF 43) drug acquisition cost for Seroxat 20mg of £17.76 for 30 tablets. It is necessary to deduct from this 7 percent of the cost to reflect the discounting reduction imposed by health boards when reimbursing community pharmacists and to add the dispensing fee paid to the community pharmacist of 95p per item dispensed.

The drug cost alone should also have the cost of a GP consultation at £7.30 added to it (Graham and McGregor, 1997) uprated from 1995/96 to 2000/01 using the BMA Health Service Cost Index (Personal Communication, BMA Health policy and Economic Research Unit, London).

Monthly drug cost = (17.76 – 7 percent)+0.95+7.3 = £24.77 per patient
Outcomes are measured at 4 months therefore 4 x 24.77 was added to the IPT-B costs (£99.08 per patient) in the sensitivity analysis

3.93 Outcomes of Therapy

The outcomes of therapy are defined as the cost per successfully treated patient, i.e. BDI ≤ 9. From the intention-to-treat Group of 59 patients receiving CBT (standard clinical practice) in the NIMH study (Elkin *et al.* 1989), a successful end point was reached in 29 cases (49 percent). From the intention-to-treat Group of 26 patients receiving IPT-B in the present study, a successful end point was reached at follow up in 12 cases (46 percent).

3.94 Cost Effectiveness

Cost effectiveness was calculated as the following:
CBT cost = 1386x59/29 = £2820 per successfully treated patient
IPT-B cost = 616x26/12 = £1335 per successfully treated patient

3.95 Sensitivity Analysis

The number of CBT sessions required was varied from 16-20 under sensitivity analysis to explore the impact on the cost effectiveness of CBT. A minimum of 16 CBT sessions will cost £1232, therefore the cost effectiveness is calculated as 1232x59/29 = £2506 per successfully treated patient. A maximum of 20 CBT sessions will cost £1540, therefore the cost effectiveness is calculated as 1540x59/29 = £3133 per successfully treated patient. This illustrates a significant cost saving with IPT-B can be realised when compared to the full quoted range of CBT sessions. In order to explore the impact of antidepressant drug useage on the cost results an extreme scenario whereby all IPT-B patients were in receipt of Seroxat 20mg daily for 4 months and no CBT patients were in receipt of antidepessants over the same time period was costed and added to the base case treatment costs:

IPT-B cost = (616+99)x26/12 = £1549 per successfully treated patient. Thus the cost effectiveness is still evident for IPT-B in comparison to the possible ranges of CBT explored.

CHAPTER 4.0

DISCUSSION

CHAPTER 4.0: DISCUSSION

4.0 SUMMARY OF THE MAIN FINDINGS

Results obtained from this study demonstrate that IPT-B leads to a reduction of symptoms of depression at a rate higher than that occurring with the passage of time (control group). IPT-B does not, however lead to an improvement in the quality of interpersonal relationships over the short duration of treatment or two-month follow up. Exploratory analyses of effect size (for reduction of symptom severity) demonstrated that all patients showed substantial improvement, whilst when stratified for initial severity, severely depressed patients showed greater improvement after IPT-B treatment than those who were less severely depressed. The greatest change, in terms of symptom reduction, was demonstrated through self-report RHRSD, whereby 73 percent of IPT-B patients made what is considered to be **clinically significant** change by two-month follow up. Sixty five percent of the IPT-B group reached Warren's (1994) criteria for success on the clinician version of the RHRSD, compared to only 39 percent in the control group. The effectiveness of IPT-B is also witnessed by the NNT results of 0.74 according to clinically significant change in BDI-II and 0.83 according to clinically significant change in RHRSD-CV. The economic evaluation extended these findings and demonstrated the relative cost effectiveness of IPT-B compared to an *estimated* standard clinical practice of CBT. The only patient characteristic to predict reliable change and severity of outcome was that of initial severity of depression. In the future, IPT-B should be tested to determine whether (a) an extended follow up period will demonstrate improvement in the quality of relationships; (b) it will outperform alternative active treatments, such as 16 sessions of standard IPT, CBT and/or pharmacotherapy (c) other patient characteristics will predict reliable change and/or severity of outcome.

4.1 INTERPRETATION OF RESULTS

The interpretation presented here will explicate the implications of the analyses in three parts, the first two of which relate to the overarching aims of IPT-B: (1) to reduce the symptoms of depression and (2) to improve the quality of interpersonal relationships

PART (1): SEVERITY OF DEPRESSION

- Primary Analyses as related to:

Hypothesis 1: *The adapted version of IPT to IPT-B is effective in reducing the symptoms of depression when compared to waiting list control.*

Hypothesis 3(a): *The adapted version of IPT to IPT-B is effective over time in terms of reducing symptoms of depression when compared to waiting list control.*

- Effect size as a measure of improvement: sample stratified for severity
- Clinical significance
- Overall impression of improvement
- Secondary analyses
- Implications of the main findings of severity of depression for service delivery

PART (2): QUALITY OF INTERPERSONAL RELATIONSHIPS

- Primary Analyses as related to:

Research Hypothesis 2: *The adapted version of IPT to IPT-B is effective in improving the quality of interpersonal relationships when compared to waiting list control.*

Research Hypothesis 3(b): *The adapted version of IPT to IPT-B is effective over time in terms of improving the quality of interpersonal relationships when compared to waiting list control.*

- Secondary analyses

The remaining sections of this chapter offer an interpretation of the findings of the following:

PART (3)

- Economic evaluation
- Strengths and weaknesses of the study
- Generalisation of the results
- Limitations of the present study and psychotherapy research in general
- Implications of the main findings in the larger scientific and professional context
- Recommendation for future research

PART (1)

4.2 SEVERITY OF DEPRESSION: PRIMARY ANALYSES as related to HYPOTHESES 1 AND 3(a)

The following section offers an interpretation of the findings of the primary analyses as related to the main hypotheses: 1 and 3(a) with regards to **severity of depression** using outcome measures for both samples including:

(1) BDI-II
(2) RHRSD-CV
(3) RHRSD-PI

4.21 Severity of Depression Outcome Measures: Hypotheses 1 and 3(a)

Table 16.0 presents the main outcome measures, within each of the sample populations, to endorse hypotheses 1 and 3(a):

HYPOTHESIS	COMPLETER SAMPLE	INTENTION-TO-TREAT SAMPLE
1: The adapted version of IPT to IPT-B is effective in reducing the symptoms of depression when compared to waiting list control.	BDI-II RHRSD-CV RHRSD-PI	BDI-II
3(a): The adapted version of IPT to IPT-B is effective over time in terms of reducing symptoms of depression when compared to waiting list control.	RHRSD-CV RHRSD-PI	BDI-II RHRSD-CV RHRSD-PI

Table 16.0: Outcome Measures to Endorse Hypothesis 1 and/or 3(a)

The following conclusions can be drawn from Table 16.0:

- Within the completer sample,[7] employment of both *clinician-rated* severity of depression (RHRSD-CV) and *patient-rated* severity of depression (RHRSD-PI & BDI-II) outcome measures **confirmed** both research hypotheses 1 and 3(a).

- Within the intention-to-treat sample,[8] employment of one *patient-rated* measure of severity of depression (BDI-II) confirmed hypothesis 1. Employment of both *clinician-*

[7] According to Elkin *et al.* (1989) the completer analysis will best reflect treatment effects for those patients who received a full course of treatment.

rated severity of depression (RHRSD-CV) and *patient-rated* severity of depression (RHRSD-PI & BDI-II) outcome measures **confirmed** research hypothesis 3(a).

Examination of the above findings allows the conclusion to be drawn that the adapted version of IPT to IPT-B **is** effective, in terms of reducing the symptoms of depression, when compared to waiting list control and remains so over time. However, Oakes (1986) has argued that statistical significance (used to draw the above conclusion) in itself, does not yield a great deal of rich information. As the overarching purpose of the present study was to estimate the **effect** of the IPT-B intervention, it was perceived that traditional statistical testing alone was not sufficient. Cohen (1990) has argued that a sufficiently large sample size and reliable assessment procedure, will result in a statistically significant result, for even trivial effects (Cohen, 1990). The fact that a treatment effect is statistically significant, as described above, reveals little about the **magnitude** of the effect and therefore effect size estimates were employed, to supplement the traditional statistics and provide a richer understanding of the treatment effects obtained.

4.3 EFFECT SIZE AND SEVERITY OF DEPRESSIVE SYMPTOMS

Prior to stratification of the samples, the effect size measures illustrated a substantial improvement in both sample populations, over all three main outcome measures (BDI-II; RHRSD-CV and RHRSD-PI). Large effect sizes were obtained (Cohen, 1988) all of which increased over time and which augmented the judgement that not only does IPT-B lead to a reduction of symptoms of depression at a rate higher than that occurring with the passage of time, patients in that group demonstrate a **substantial** improvement.

When the samples were stratified by initial severity of depression, the results indicated that severely depressed patients demonstrated greater improvement than those who presented with less severe symptoms of depression, on all major measures of outcome. This finding is consistent with results obtained for the regression analyses, conducted in the present study and similar to the results reported by Brown, Schulberg and Prigerson (2000) in their study of Primary Care patients in the US, whereby lower depressive symptom severity at 8-months was associated with higher baseline functioning (higher depressive symptom severity at follow-up was associated with lower baseline functioning in the present study).

[8] Results of the intention-to-treat analysis may be considered an estimate of the overall performance of a treatment programme, including its ability to retain patients in treatment.

Brown *et al.* (2000) also reported that less severely depressed patients (baseline HRSD≤19) prescribed nortriptyline, improved more rapidly during the initial 3 months of treatment than clinically similar patients provided with IPT. Both IPT and nortriptyline were comparably effective in treating major depression among severely depressed patients (HRSD≥20). Comparisons with Brown *et al.* (2000) will only be made in light of the inherent differences between the US and the UK health services, the clinical sample and only when a pharmacotherapy arm is included in a trial with IPT-B in the future. A question is raised by this finding though, in terms of the rate of therapeutic change: would IPT-B have an effect, as rapid as that observed with nortriptyline (in less severely depressed patients) in the initial stages of treatment, if the patient is aware of the imposed brief time-limit as in IPT-B, i.e. would the rate of therapeutic change be accelerated? Perhaps one of the reasons for the differential early effects in Brown's study was that in the IPT group, patients knew that they had approximately 20 sessions and therefore change *could* take longer, as has previously been suggested by Eckert (1993).

Therefore, perhaps one of the reasons for the observed changes, of substantial effect, in the present study, despite such a short intervention period, is precisely *because* of the explicitly imposed brief time-limit. It is suggested that perhaps the shorter time-limits may change the impact of the sessions processes on the patients. The only way to determine this would be to observe the temporal patterns of session impact on patients across different treatments and examine whether these patterns show evidence of acceleration in the 8-session treatments as compared with 16 session treatments; this is discussed further with regards to extending the present study.

The effect size measures suggest the relevance in the future of stratifying the sample at the outset, as there were quite clear differences between those who were severely depressed at baseline and those who were less severely depressed, in terms of the effect of IPT-B.

4.4 EXAMINATION OF CLINICAL SIGNIFICANCE IN TERMS OF SEVERITY OF DEPRESSION

One problem with the above effect sizes is that they compare differences in mean scores against the standard deviations of the groups, rather than against any absolute standard. The presence of a large effect size therefore does not guarantee that a result is clinically significant. Shapiro, Barkham, Hardy, and Morrison (1990) suggest that indices of clinical significance should be incorporated into studies where clinical change is being assessed and therefore were applied to the present study.

It is interesting to note that the clinical significance of research findings has been neglected until fairly recently. Indeed, in the NIMH TDCRP study, the clinical significance of client change was considered by determining the number of patients *"who met a predefined level of clinical recovery"* (Elkin *et al.*1989, p974) but the reliability of the change was **not** considered. The method used by Elkin *et al.* (1989) did not consider the possibility of reliable deterioration during treatment for some individuals. Ogles *et al.* (1995) addressed these issues and reanalysed the data from the NIMH study and applied the Jacobson method (Jacobson and Truax, 1991) to the TDCRP data stating that a relatively large number of patients who received treatment for depression made reliable improvements. As in the present study, the reports were not limited to the patient's self-report of current symptoms of depression but were also evident to a clinician and on self-report measures of diverse psychological symptoms. One of the benefits of the Jacobson method is that it allows one to certify that changes are reliable and indeed, a relatively large number of patients receiving IPT-B made reliable improvements, in terms of severity of symptoms, from baseline to two month follow up. The present findings suggest that IPT-B for Major Depressive Disorder in Primary Care can result in clinically meaningful changes in a relatively short period of time and those changes can be maintained and even increase over a two-month follow up.

It is also interesting to examine the reliable changes that took place within the waiting list control group, which were not surprising given the results from the NIMH study. A substantial number of patients in the placebo-clinical management group met criteria for meaningful improvement (i.e. as a direct comparison, 62 percent of all patients on BDI for NIMH as compared to 39 percent for BDI-II in the present study). When considering each of the main severity of depressive symptom outcome measures, the two groups differed. IPT-B had a higher proportion of patients who met the criteria for clinically significant change

across all 3 measures (66 percent, 73 percent and 64 percent for RHRSD-CV, RHRSD-PI and BDI-II respectively) whereas the control group had a lower proportion (50 percent, 55 percent, and 40 percent for each measure respectively).

4.41 Reliable Deterioration in terms of Severity of Depressive Symptoms

Whereas a number of clients experienced reliable changes for the worse in the NIMH TDCRP only one patient (in both samples) in the IPT-B treatment group experienced reliable deterioration. The potential negative outcomes that occur during psychotherapy are well documented (Lambert, Shapiro and Bergin, 1986) and findings in the present study suggest smaller proportions of negative change, e.g. 4 percent on both self report measures but no reliable deterioration was detected using clinician rating of change.

4.42 The Issue of Discordance among Multiple Measures of Outcome

Discordance among multiple measures of outcome is not a new phenomenon but has been a problem for researchers for many years (Lambert *et al.* 1986). Various instruments used in outcome research may create large differences in improvement rates or treatment success (Ogles, Lambert, Weight and Payne, 1990) and indeed, instruments completed by different parties involved in the treatment often have divergent views of success (Pilkonis, Imber, Lewis and Rubinsky, 1984). One potential problem of measurement concordance involves the possibility that patients will be identified as functional at pre-treatment (Saunders, Howard and Newman, 1988), i.e. they may reach the level required on one instrument as cutoff for inclusion but not on another. Inclusion criteria are detailed in Chapter 3.0 and included the diagnosis of Major Depressive Disorder according to DSM-IV criteria (APA, 1994). However, three patients had a baseline score on the BDI-II in the functional range (BDI-II < 12). Because of floor effects, these patients had little chance of making reliable change in the improvement direction and therefore were unlikely to be counted in the clinically significant improvement group. Therefore, the finding that 73 percent of the IPT-B group had made a reliable change on the BDI-II by the end of two-month follow up is, at best a conservative conclusion.

Despite multiple measures sometimes presenting a discordant picture of change, findings from the Ogles *et al.* (1995) study and the present study provide hope that clinical significance, as measured by multiple methods can be quite precise. When limited to three

outcome measures appropriate for assessing change after treatment (as in the present study) for depression, the agreement among measures is impressive.

4.43 Overall Impression of Improvement in terms of Severity of Depression and Summary of Effects of IPT-B

One final method of definition of a 'successful treatment' was through application of criteria as outlined by Warren (1994). When applied to the results of the present study, in terms of symptom reduction on both versions of the RHRSD, it was revealed that when clinician rated, 65 percent of the IPT-B group reached criteria for success by 2-month follow-up versus 39 percent in the control group. When self-rated, 54 percent of the IPT-B group reached criteria for success by two-month follow-up, compared to only 39 percent control group. By Warren's (1994) criteria therefore, IPT-B can certainly be defined as a successful treatment for the majority of patients presenting to Primary Care in the present study and certainly more successful in terms of reduction of symptoms of depression than the waiting list control group. It is interesting to note that application of Warren's criteria for success appears to be stricter than the Jacobson method for clinically significant change as although still substantial, less patients reached criteria for success according to Warren than they did when using Jacobson's method. Therefore, in the future, it is recommended that not only should the Jacobson method be employed to define clinically significant change but if using the RHRSD, the more stringent criteria of Warren (1994) should also be employed.

Results from the effects on the IPT-B treatment calculations, according to Greenhalgh (1997), demonstrated that when clinically significant change (Jacobson and Truax, 1991) was used as the outcome event, the number needed to treat (NNT) was less than one. As the number needed to treat was so small, the intervention of IPT-B is considered to be worthwhile.

When the results of the severity of depression were examined in greater depth, Post Hoc analyses for the BDI-II demonstrated that although there were significant differences between baseline and two-month follow up for the control group, in both samples, the differences were not as great as those described for the IPT-B group. One possibility for these findings is that the results within the control group are a reflection of spontaneous recovery over time, which will occur in some patients without any intervention (Roth and

Fonagy, 1996). It is argued that the rate of observed spontaneous recovery will depend on the point in time, over the natural cycling of a disorder, at which treatment is offered. Spontaneous recovery may be seen as a reflection of the natural history of major depressive disorder and highlights one of the problems faced by the current trial: **to demonstrate that the treatment of IPT-B had a gain beyond the natural recovery,** which it did through the significant differences obtained between the IPT-B group and the control group, on severity of depression outcome.

4.5 SECONDARY ANALYSES ASSOCIATED WITH SEVERITY OF DEPRESSION

In an effort to understand the variability of response to treatment for depression, patient characteristics have received much attention, with little consistency in the findings. Elkin *et al.* (1989) in the original NIMH TDCRP found that marital status was significantly related to outcome and better outcome has been reported in patients in a long standing relationship or married (e.g., Elkin, 1994; Elkin, Parloff, Hadley and Autry, 1985). Marital status was **not** related to outcome in the present study, which was not as expected given the evidence that marital relationships have a high correlation with and etiological implication for the onset of depression and have also been demonstrated to have an effect on patients' responsiveness to and maintenance of treatment gains (Rounsaville, Weissman, Prusoff and Hercet-Barob, 1979; Rounsaville, Prusoff and Weissman, 1980). One possible explanation for this finding is the high proportion of married participants in the study; more than 60 percent of participants in each group, in both samples were married. The data however, does not differentiate those participants who were in marital conflict and indeed, the categorisation of 'married' assumes a harmonious partnership. In the future, categorisation of the 'marrieds' should be those who describe themselves as in a harmonious relationship and those who describe themselves as in a relationship of conflict.

4.51 Predictors of Outcome for Severity of Depression

The only patient characteristic to demonstrate a linear relationship with outcome was that of initial severity of depression, therefore in order to determine whether the initial severity of depression could **predict** outcome, the following ways of quantifying outcome were used:
(1) Reliable Change Index (Jacobson and Truax, 1991) i.e. how much a patient had changed from baseline to both end of treatment and 2-month follow up, employing the Reliable Change statistic for both BDI-II and RHRSD and (2) Severity of depression, as measured by BDI-II and RHRSD at end of treatment and 2-month follow up.

The results for the two major severity of depression outcome measures demonstrated that the only predictors of reliable change, as a result of IPT-B, are their respective baseline measures which is an important finding, particularly for those in Primary Care. The BDI-II is a relatively straight forward questionnaire for the patient to complete and could be administered by the GP when considering a patient for a course of IPT-B. The baseline score could be used to predict the reliable change. It is argued that the clinician administered RHRSD is too time consuming for the GP to administer but would be part of the process of IPT-B during the initial stages and could therefore be used by the IPT-B therapist to predict reliable change. The result of this finding, it is argued, will enable the IPT-B Therapist to adopt a hopeful, supportive and active stance, particularly with those who are more severely depressed, as they can expect the most change.

The results from the second measures of outcome allowed the judgement that self report on the BDI-II at baseline was a significant predictor of severity at follow up, therefore, not only does the BDI-II predict reliable change, it will also predict severity of outcome. The results for the clinician version of the RHRSD were not as positive and indeed, the findings in the present study indicate that severity of outcome cannot be predicted using the clinician version of the RHRSD.

4.52 Predictors of Outcome and Future Research

In the future, any research concerning IPT-B should take account of the existing literature with regards to factors which have been demonstrated to be related to outcome with IPT:

Factor Associated with Outcome in terms of Improved Symptomatology	Author(S) and Year of Publication
Severity of depressive symptoms	Brugha *et al.* (1990); Ramana *et al.* (1995)
Patient contribution to the alliance and the perceived quality of the therapeutic relationship	Zuroff *et al.* (2000)
Functional disability	Coryell, Endicott, and Keller (1990)
Medical comorbidity	George, Blazer, Hughes and Fowler (1989); Keitner, Ryan, Miller, Kohn and Epstein (1991)
Personality pathology	Shea, Widiger and Klein (1993); Ezquiaga, Garcia, Bravo and Pallares (1998); Patience, McGuire, Scott and Freeman (1995)
Psychosocial factors such as the occurrence of stressful life events	Monroe, Kupfer and Frank (1992); Vallejo, Gasto, Catalan, Bulbena and Menchon (1991).
Social support	George, Blazer, Hughes, & Fowler, (1989); Veiel, Kuhner, Brill and Ihle (1992)
Patient's belief about the controllability of their health	Reynaert, Janne, Vause, Zdanowicz and Lejeune (1995)

Table 17.0: Clinical Factors Associated with Outcome from Major Depressive Disorder

It is also advised that a measure of therapist competence, both as a check for integrity of the independent variable and for its potential as a predictor variable in analyses of outcome, be included in any future research involving IPT-B (Shaw *et al.* 1999).

It is important to consider that the majority of studies which have examined recovery from depression have been conducted with psychiatric samples. Until recently, few investigations had examined clinical characteristics or psychosocial factors associated with treatment outcome in the Primary Care population and even fewer have examined those factors within the Primary Care population within the NHS in the UK. The studies cited above suggest that similar clinical factors such as depressive severity, disability and medical and psychiatric comorbidity are associated with treatment outcome in both depressed Primary Care and psychiatric patients.

An understanding of the patient factors which are associated with or even predict good outcome for specific treatments will permit clinicians to customise depression interventions to particular patient profiles and to minimise relapse or recurrence. Certainly, in the future, any trial using IPT-B should take account of both clinical and psychosocial factors and perhaps beliefs about health (Brown *et al.* 2000) to determine if any are associated with or can predict outcome. Brown *et al.* (2000) stated that in their sample of Primary Care patients (from the US) health beliefs were the only significant predictor of symptom reduction for patients in the IPT group. In the present study, baseline severity of depressive symptoms was found to be the only significant predictor of symptom reduction.

4.6 IMPLICATIONS OF THE MAIN FINDINGS OF SEVERITY OF DEPRESSION FOR SERVICE DELIVERY

A number of questions are raised by the findings from the present study, in terms of the direct implications for service delivery. With regards to the severity of depressive symptoms, it is possible that when a brief time limit is imposed as in IPT-B, the rate of therapeutic change is accelerated, as has previously been suggested by Eckert (1993). It is possible that change occurred within the IPT-B group due to high levels of therapist activity, establishing specific and limited clear goals within the IPT-B model, maintaining a clear, collaboratively agreed focus and setting an explicit time limit from the start of therapy (Reynolds *et al.* (1996). Although these features have previously been described as potential catalysts of change for brief therapy (Davanloo, 1978; Malan, 1976; Mann and Goldman, 1982 and

Sifneos, 1979) they are also very clear features of the IPT-B model, in terms of the overall characteristics and non-specific factors (Table 3.0). These features, although highlighted in the IPT-B model, are not specific to IPT-B, therefore from the results obtained, we cannot determine whether it is IPT-B *per se* that is creating the change, but we can conclude that the 8 sessions of *therapeutic contact* is more effective at reducing symptoms of depression than waiting list control. Further research to determine the specificity of the model of IPT-B is now called for, as within the present design, there is an obvious lack of comparison group for specificity. Indeed, the comments made above with regards to accelerated time limits could also be applied to the CBT model of depression. In order to examine the possible differential acceleration of changes in psychotherapy, further research including CBT with 8 and 16 sessions is now called for, as is discussed in terms of further research.

According to DeRubeis and Crits-Christoph (1998), a psychotherapeutic approach can only be termed 'efficacious' if it (a) leads to a reduction or remission of the disorder at a rate higher than that occurring with the passage of time or (b) outperforms an alternative active treatment. The present study certainly met the first criteria, as it was originally designed to do, but not the specificity criteria.

PART (2)

4.7 QUALITY OF INTERPERSONAL RELATIONSHIPS: PRIMARY ANALYSES as related to Hypotheses 2 and 3(b)

The following section offers an interpretation of the findings of the primary analyses as related to the main hypotheses: 2 and 3(b) with regards to **the quality of interpersonal relationships** using outcome measures for both samples including:

(1) SOS-B
(2) WHOQOL-Bref

4.71 Quality of Interpersonal Relationships: Hypotheses 2 and 3(b)

Research Hypothesis 2: *The adapted version of IPT to IPT-B is effective in improving the quality of interpersonal relationships when compared to waiting list control.*

Research Hypothesis 3(b): *The adapted version of IPT to IPT-B is effective over time in terms of improving the quality of interpersonal relationships when compared to waiting list control.*

There is evidence that the original model of IPT has an effect on social adjustment that goes beyond the effects of drugs and that builds over time, following treatment termination (Weissman *et al.*1974, 1981) and the results obtained in the present study would appear to support that observation. The perceived quality of interpersonal relationships was examined through the use of SOS-B and the social relationships domain of the WHOQOL-Bref, with a result of a clear effect with time in both sample populations. Indeed, it was a consistent finding that the passage of time alone had the main effect, in terms of improving the quality of interpersonal relationships. As there were **no significant differences** reported between the two groups for either emotional or practical support (SOS-B) or for the quality of social relationships (WHOQOL), both ***research hypotheses 2 and 3(b) were rejected.***

A possible explanation for the lack of differences between the two groups, with regards to the quality of interpersonal relationships, is that the follow-up time period may have been too

short to determine any real changes within the patients' interpersonal world. What remains unclear from the results is whether the differences obtained over time would continue in the IPT-B group and gradually level off in the control group, as has been suggested, for example by Weissman *et al.*(1981). Not only is the intervention time very brief (8 weeks) but so too is the follow-up period, therefore although one of the main aims of IPT is to improve the quality of interpersonal functioning, perhaps within the IPT-B model the aim should rather be to improve the interpersonal functioning **over time** as would be determined through longer follow-up (approximately 6 months).

4.8 SECONDARY ANALYSES

The remaining three domains of quality of life were analysed as secondary analyses, as they did not directly relate to the main research hypotheses.

4.81 Psychological, Environmental and Physical Capacity Domains of the WHOQOL-Bref

Within the *psychological* domain, there were clear differences found between the two groups, in both samples, which demonstrated that those in the IPT-B group reported a significantly better quality of life within this domain after intervention. Indeed, within the completer sample, IPT-B was effective over time in terms of improving the perceived quality of life within the *psychological* domain, when compared to waiting list controls; this result was not unexpected, as with any psychological intervention, the quality of life in the psychological domain would be expected to improve.

The *environmental* and *physical capacity* domains were not as definite though; improvement in the environment and/or physical capacity would not necessarily be expected to be associated with a psychological intervention. Within the *environmental* domain, the findings suggest clear differences over time showing that as time progresses, the subsequent perceived quality of life within this domain improves. Within the completer sample, not only was there a clear difference between the two groups, but IPT-B was shown to be effective over time in terms of improving the perceived quality of life when compared to waiting list controls.

In terms of the *physical capacity* domain, results demonstrated clear differences over time, within both samples, again showing that as time progresses, the subsequent perceived quality

of life within this domain improves. Within the intention-to-treat sample, significant differences between the two groups showed that those in the IPT-B group reported significantly better quality of life within the *physical capacity* domain than those in the control group, after intervention.

Therefore, IPT-B can be observed to be associated with a difference in the reported perceived quality of life within the psychological, environmental and physical capacity domains. One possible explanation for these findings, despite neither the environment nor physical capacity being a goal of IPT-B, is that those who are more depressed are unable to take pleasure in their environment and therefore perceive the quality of it to be negative. As the severity of depression decreases, mood lifts and energy levels improve, patients may be able to take more interest in their environment, and therefore perceive the quality of it to be improving. The same hypothesis could also be applied to physical capacity; as depression severity decreases, energy levels improve and the patient is able to move around without expending as much energy as when severely depressed and therefore perhaps perceive their physical capacity to have improved.

Therefore, not only is IPT-B associated with a positive effect on depressive symptoms in the short term, it can also be associated with a positive influence on the patient's perception of the quality of their *environment*, *physical capacity* and *psychological well-being* (as there were significant differences observed between the two groups for each of these domains). In the future, it would be interesting to observe those patients who have made reliable improvement, using Jacobson's reliable change index (Jacobson and Truax, 1991) to determine whether greater reliable change in depressive symptomatology is associated with greater improvement in quality of life, in terms of perceived *environment, physical capacity* and *psychological well-being*. As discussed earlier, this would also act as a response to the call for data on quality of life (Gladis *et al.* 1999) and perhaps become one of the central outcome measures as suggested by Chambless and Ollendick (2001).

PART (3)

4.9 ECONOMIC EVALUATION

The economic evaluation was carried out in response to the following suggestion:

"We believe that any judgement of the clinical significance of treatment effects is best made in the context of treatment costs. The most practical treatments will be those with benefit-to-cost ratios that are higher than those of other available treatments."

DeRubeis and Crits-Christoph (1998)p38

4.91 Discussion of Sensitivity Analysis

The main assumption that was made in the economic evaluation, was the number of Clinical Psychology sessions required to deliver CBT; the assumption was that 18 sessions would be necessary. When this number was varied between 16 and 20, under sensitivity analysis, it did not effect the direction of the outcome of the cost effectiveness analysis, indicating that the results are robust to changes in this major variable.

In addition, the effect of adding the cost of antidepressant drugs to the IPT-B costs was explored and it too did not effect the direction of outcome of the cost effectiveness analysis.

The outcome measure of BDI-II was chosen, as published data existed, which were directly comparable to the data collected for the current study. It must be noted, however that the success rate, as indicated by BDI-II was considerably lower than that indicated by other outcome measures, thus providing a conservative measure of cost effectiveness. The cost effectiveness of CBT is £2820 compared to £1335 for IPT-B, demonstrating the superior cost effectiveness of IPT-B. It should be noted that this economic evaluation has been carried out from the perspective of the NHS only. If it had been within the scope of the study to adopt a societal perspective, it would have been necessary to include the costs to the patients and to the economy, as well as to the NHS. Effectively, this would make IPT-B even more cost effective, as it is delivered over a considerably shorter period of time, therefore inconveniencing the patients must less and returning them to full functioning earlier.

5.0 STRENGTHS AND WEAKNESSES OF THE PRESENT STUDY

5.01 Summary of the Strengths of the Present Study

The major strengths of the present study can be summarised as follows:

1. The adaptation of IPT to IPT-B was carefully planned and executed according to suggestions made by Wilfley *et al.* (1998) and subsequently compared to both IPC and IPT.

2. Positive results from the initial pilot case-study provided justification for the present study.

3. Sources of potential **systematic bias** (defined as anything that erroneously influences the conclusions about the groups and distorts comparisons) were acknowledged and avoided whenever possible. The aim in the present study was for the two groups to be as similar as possible, except for the particular difference being examined (intervention of IPT-B) which was confirmed through initial statistical analysis which revealed no significant differences between the treatment group and the control group at baseline for the major outcome measures, for either of the sample populations. Sources of bias were checked and monitored according to advice provided by Greenhalgh (1997) shown in Figure 5.0.

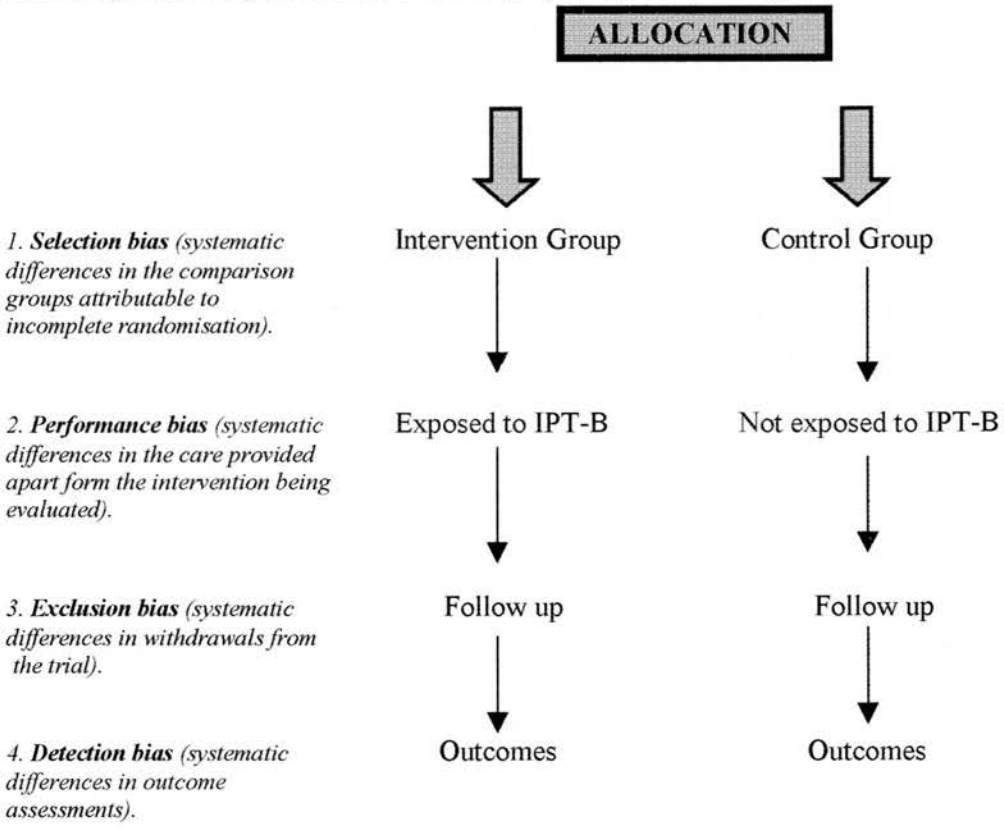


Figure 5.0: Sources of Potential Bias

4. **Effect size** estimates were employed to supplement the traditional statistical analyses conducted and therefore provided a richer understanding of the treatment effects.

5. Examination of the **clinical significance** of the results and comparison with results obtained from a reanalysis of the NIMH TDCRP data (Ogles *et al.* 1995) allowed the judgement that the changes made within the present study, in terms of severity of depressive symptoms, were reliable.

6. Examination of two sample populations, i.e. **completer** and **intention-to-treat**, ensured that an accurate representation of the findings was delivered. Simply ignoring patients who drop out from a clinical trial will bias the results, usually in favour of the intervention. It is therefore standard practice to analyse the results on an intention to treat basis (Stewart and Parmar, 1996).

7. The **economic evaluation**, which was conducted alongside the study, has ensured that IPT-B is now one of the more practical treatments, according to DeRubeis and Crits-Christoph (1998). Economic evaluations are beginning to occur more frequently within psychotherapy outcome research and presumably will become standard practice in the future. The economic evaluation conducted alongside the present study will allow comparison with other psychotherapy outcome trials in the future.

8. The detailed case-studies of 'successful' and 'unsuccessful' IPT-B (Appendix 2.0) provide information about the benefits and problems of IPT-B treatment in clinical practice.

5.02 Summary of the Weaknesses of the Present Study

The following have been identified as potential weaknesses of the present study:

1. Within the present design, there is an obvious lack of comparison group for specificity. According to DeRubeis and Crits-Christoph (1998), a psychotherapeutic approach can only be termed 'efficacious' if it (a) leads to a reduction or remission of the disorder at a rate higher than that occurring with the passage of time or (b) outperforms an alternative active treatment. The present study certainly met the first criteria but not the specificity criteria.

2. The lack of stratification of atypical features of depression was considered to be a potential weakness of the present study, as there are reports of differential response to pharmacotherapy versus psychotherapy (Sotsky, 1997).

3. The lack of consistent completion of patient dairies (to account for external bias) was considered as a weakness of the present study but as highlighted earlier, concerns about compliance with paper diaries are justified (Stone *et al.* 2002) and is not a reflection of this particular study but is a common finding in other health care settings and in other research trials. It is therefore proposed that different methods of obtaining that information be piloted, such as adding a 5-minute 'diary completion' section to either the beginning or end of the session for each arm of future trials.

4. The lack of blind ratings is a clear weakness and source of potential bias in the present study but given the resource implications, it was considered that in this preliminary stage of examination of IPT-B, the benefits outweighed the costs.

5. There was only one therapist involved in the delivery of IPT-B, however as described above, given the resource implications it was the only feasible design and attempts *were* made to overcome this potential source of bias, through the employment of an independent rater of audiotaped therapy sessions.

5.03 Summary of Factors Considered to be both a Strength AND a Weakness

1. It is generally accepted that the only satisfactory method of assigning treatments in a clinical trial is by randomisation however, there is also an argument that **because** patients in treatment in the community are not randomly assigned to treatment, the results are unlikely to generalise to clinical practice. There are, of course both advantages and disadvantages to the process of randomisation, for example, it may rule out selection bias as a threat to internal validity and it allows the use of the statistical theory of error. The process of randomisation however, does not take account of patient choice (Brewin and Bradley, 1989) which is a clear weakness.

2. Therapist integrity and adherence to the model of IPT-B was monitored and rated by an experienced objective Clinical Psychologist (trained in IPT) through audio-taped sessions. Although this may be considered one of the sources of strength of the study, in clinical

practice, it would be unusual to audiotape every session and formally rate adherence to the model, therefore this actually had an effect of potentially limiting the generalisability of the results and thus becoming a weakness.

3. The use of specific manuals within the present study will ensure that the results are capable of replication and are *"necessary to provide an operational definition of the intervention under study"* (Chambless and Ollendick, 2001) but in terms of the generalisability of the results there are two main arguments: (1) Seligman (1996) and Garfield (1996) suggest that therapists in the community (in the US) do not follow manuals and therefore the results are not generalisable. Indeed, according to Addis and Krasnow (2000), nearly half of licensed psychologists in the US **never** use manuals in their clinical work. (2) Without a manual to describe what the treatment entails, clinicians are unable to determine the similarity of their own practice. In terms of generalisable knowledge, it is therefore meaningless to say that a treatment works without being able to say what that treatment is (Chambless and Ollendick, 2001). This is a controversial issue in psychotherapy research and interestingly, Chambless and Ollendick (2001) have recently reported that there is no data to support the assertion that manualisation of psychotherapeutic treatment is detrimental to patients.

As Fonagy (1999) has mentioned in his psychodynamic perspective on the general acceptance of treatment manuals, some clinicians react negatively to such, perhaps perceiving a threat to their independence of practice. Indeed, Bohart, O'Hara and Leitner (1998) stated that the therapist is a *"...disciplined improvisational artist, not a manual-driven technician"* (p145). Some other authors perceive manualisation as being more positive: Wilson (1998) stated that *"...use of standardised, manual based treatments in clinical practice represents a new and evolving development with far-reaching implications for the field of psychotherapy"* (p363). In terms of the present study, it was considered to be meaningless to report any data concerning an adapted model of IPT, without stating exactly what such a treatment entailed and without providing direct comparisons with other models (IPT and IPC). All of the above strengths and weaknesses represent the balance between high internal vs external validity and are summarised in Appendix 14.0.

Perhaps the most important question to be asked of any study, whereby a treatment has been adapted to a new format however is: ***will this treatment be of use to other clients and clinicians, i.e. will this treatment generalise?***

5.1 GENERALISATIONS AND IMPLICATIONS OF THE MAIN FINDINGS TO THE PROFESSIONAL CONTEXT

5.11 Generalisations of Main Findings

The most obvious limitation of the present study is that it is not clear if the results from this study would be relevant to other cases, not randomised to a controlled trial. This concerns the external validity or generalisation of findings from the experiment, so that it can be answered empirically. The present study considered two domains to which the findings of the study may be generalisable:

5.111 Population validity: to which members of which population is IPT-B useful or applicable?

Results indicate that the original model of IPT can be adapted to a briefer format, IPT-B, and used within Primary Care. Results also demonstrate that IPT-B is effective in reducing symptoms of depression. The procedure proved to be useful for those patients presenting to their GP who considered depressive symptoms as their **main** problem (see inclusion and exclusion criteria) and were willing to undergo a process of randomisation for the trial.

5.112 Ecological validity: how far can these findings be replicated with different experimenters, settings and measurement procedures?

To date, all reported adaptations of IPT have used trained IPT therapists. In the early stages of the adaptation, the results of this study can only be applied to those trained in IPT. The therapy took place in Primary Care and therefore, the results cannot be said to be applicable to other settings as yet.

5.12 Implications of Main Findings

The overarching research question which was posed at the beginning of the present study was: *Can Interpersonal Psychotherapy of Depression (IPT) be adapted to be briefer (IPT-B) within a Primary Care setting and still remain effective in terms of reducing the symptoms of*

depression and improving the quality of interpersonal relationships? From the results presented, the following implications for clinical practice can be made:

1. IPT **can** be adapted to be a briefer model of IPT-B.
2. IPT-B can be employed with patients who present to their GP (in Primary Care in the UK) with a primary diagnosis of major depressive disorder.
3. Patients who receive IPT-B can expect to make an improvement in terms of reducing the presenting symptoms of depression.
4. Patients who are more severely depressed can expect to make more substantial improvements, in terms of reducing their symptoms of depression, after IPT-B treatment than those who are less severely depressed.
5. The initial severity of depression will predict *reliable* change as a result of IPT-B.
6. IPT-B is considerably more cost effective than an *estimated* routine treatment of CBT.
7. In order to achieve one success with IPT-B, the number needed to treat was less than one patient, which is considered to be extremely small.
8. Training in IPT may include a section on adapted models (as discussed earlier) and include IPT-B and the altered time limits.

5.2 LIMITATIONS OF THE PRESENT STUDY and PSYCHOTHERAPY RESEARCH IN GENERAL

The following section is a brief discussion of a selection of the wider issues, considered to be of most relevance to the present study. The issues presented here may also be considered as limitations within the present study and within psychotherapy research in general.

5.21 The Issue of Attrition

Elkin *et al.* (1989) found that their Early Terminators were more severely depressed at intake than patients who completed treatment which was not found in the present study. Indeed, only 4 patients dropped out of treatment, all of whom had received at least 4 sessions of IPT-B and only one of whom was severely depressed at intake. The present study attempted to take account of those patients who dropped out through use of the intention-to-treat sample.

5.22 Length of Follow Up

An interesting observation is that the greatest change in the present study was demonstrated through self-report on the RHRSD, whereby 73 percent of patients rated themselves as making a clinically significant change, on a reduction of depressive symptom basis, by 2-month follow up. In the IPT-B intervention group, all initial changes observed at the end of treatment were maintained through to 2-month follow up. Roth and Fonagy (1996) however, state that the effectiveness of a treatment cannot be judged simply by the management of an index episode; reduction in relapse is a more pertinent and informative guide to success. They also suggest that long term follow-up of at *least* 2 years would be necessary to provide a conclusive result that is not confounded with the natural history of Major Depressive Disorder.

The brief 2-month follow up period did not allow sufficient time to determine if IPT-B had any impact on the quality of interpersonal relationships or indeed, if treatment gains were maintained.

5.23 Use of DSM-IV Diagnosis for Major Depressive Disorder (MDD)

As most recent research on outcome employs DSM as the basis for patient selection, so too did the present study. Use of diagnostic labels to select patients however, has the potential to create an illusion of homogeneity, which often fails to mirror the complexity of clinical work (Roth and Fonagy, 1996). There are advantages to using the DSM system, in particular, its operationalised criteria, which provides a clear conceptual framework. The use of diagnostic labels in the majority of outcome studies also increases the potential to make generalisations. It is argued here that without some categorisation, synthesis of evidence would be extremely difficult, if not impossible. Despite the limitations of the DSM criteria however, a feasible alternative has yet to be suggested.

Therefore, the use of diagnostic labels, as assigned through the use of DSM criteria, raises the question of diagnostic homogeneity i.e. ***was the sample diagnostically homogenous?*** All patients certainly reached criteria for major depressive disorder (MDD), according to DSM-IV, but some patients also reached criteria for dysthymic disorder (10 percent of total sample population were diagnosed with MDD superimposed on dysthymic disorder). The same proportion of patients were diagnosed with comorbid generalised anxiety disorder (10 percent), which in itself raises the issue of ***comorbidity*** and the related issue of whether or not atypical features of major depressive disorder should have been identified. Stewart,

Garfinkel, Nunes, Donovan and Klein (1998) stated that comparisons of treatments may be misleading if studies do not account for diagnostic subtype. However, they also concluded that the NIMH

TDCRP data did **not** show differential treatment effects within the psychotherapies, for patients with and without atypical features. This finding may have been due to small sample size and therefore, it is the recommendation that any future trial with IPT-B differentiates the sample prospectively, rigorously applying DSM-IV criteria for atypical features of depression.

5.3 RECOMMENDATIONS FOR FURTHER RESEARCH

5.31 Efficacious method versus effectiveness studies: the balance between strict conditions and 'real life'

Efficacy studies refer to well-controlled outcome research in which the treatment groups are compared to a control group and/or to another treatment group under strict experimental conditions. Such studies require quite rigid scientific control, with the treatment groups differing only in the specific factor of interest. It can be appreciated that while efficacy studies are necessary sub-components of therapy, and for the testing of scientific theories, they provide little information about the benefits and problems of treatment in routine clinical practice, which the present study sought to determine. Indeed, the real benefits and problems of IPT-B came from the detailed case studies (Appendix 2.0).

The present study design is certainly not reflective of routine clinical care, i.e. patients are not routinely randomised into two groups; therapy is not routinely manualised; adherence to a model of therapy is not routine clinical practice; a predetermined number of sessions is not routine clinical practice and inclusion criteria are not routinely applied to each patient. Patients do not routinely agree to maintain a stable dose of antidepressants during therapy as they agreed to in the present study. However, despite these differences between routine clinical practice and the present study, the design was not as rigorous as would be found in a Randomised Controlled Trial, which can be expensive, time-consuming and clinically invasive.

In the consideration of future studies of IPT-B, it is important to acknowledge some of the potential disadvantages of the 'Gold Standard' Randomised Controlled Trial as follows:

1. The method used to randomise may allow the clinician to know in advance to which group the patient is going to be allocated (imperfect randomisation).

2. All eligible patients may not be subjected to randomisation (selection bias).

3. A high number of patients may refuse to enter the randomisation procedure.

4. It may be difficult to achieve genuine independence of assessment in long-term psychological interventions and assessors will not be blind as to which group the patients have been assigned. In terms of the present study, the assessor was certainly not blind to the treatment group.

5. An RCT requires a sample which is as homogeneous as possible (i.e. meeting criteria for a single diagnostic category) and the identification of a main target outcome. These criteria would exclude all patients with co-morbid disorders which again, certainly was not the case in the present study and is certainly not a true reflection of patients presenting to Primary Care. As the RCT requires a highly selected population with a given condition, it makes the RCT sample unrepresentative of the population treated in clinical practice. Therefore results from the RCT cannot be translated into clinical recommendations as they pertain to an unrepresentative sample. The sample in the present study were certainly more representative of the clinical sample presenting to the GP's as the entry criteria were, by design, less rigid than a full RCT would demand.

6. In a full RCT, there would be different therapists employed to deliver the therapy of each arm of the trial The strict requirement of the RCT would demand that therapists be of comparable experience and all trained in the delivery of manualised treatment. Assessing video or audio recordings would then ensure treatment adherence.

Despite arguments from Seligman (1996) that effectiveness studies are important sources of information for empirically validating treatments and that data derived from such may be more persuasive than efficacy studies, it is recommended that IPT-B be subjected to a comparative RCT. As Shapiro (1989) stated, outcome research design is about compromises, which are based on the explicit understanding of the implications of the choices made. It is now recommended that, despite the limitations, an RCT should be conducted, using the design as depicted in Figure 6.0.

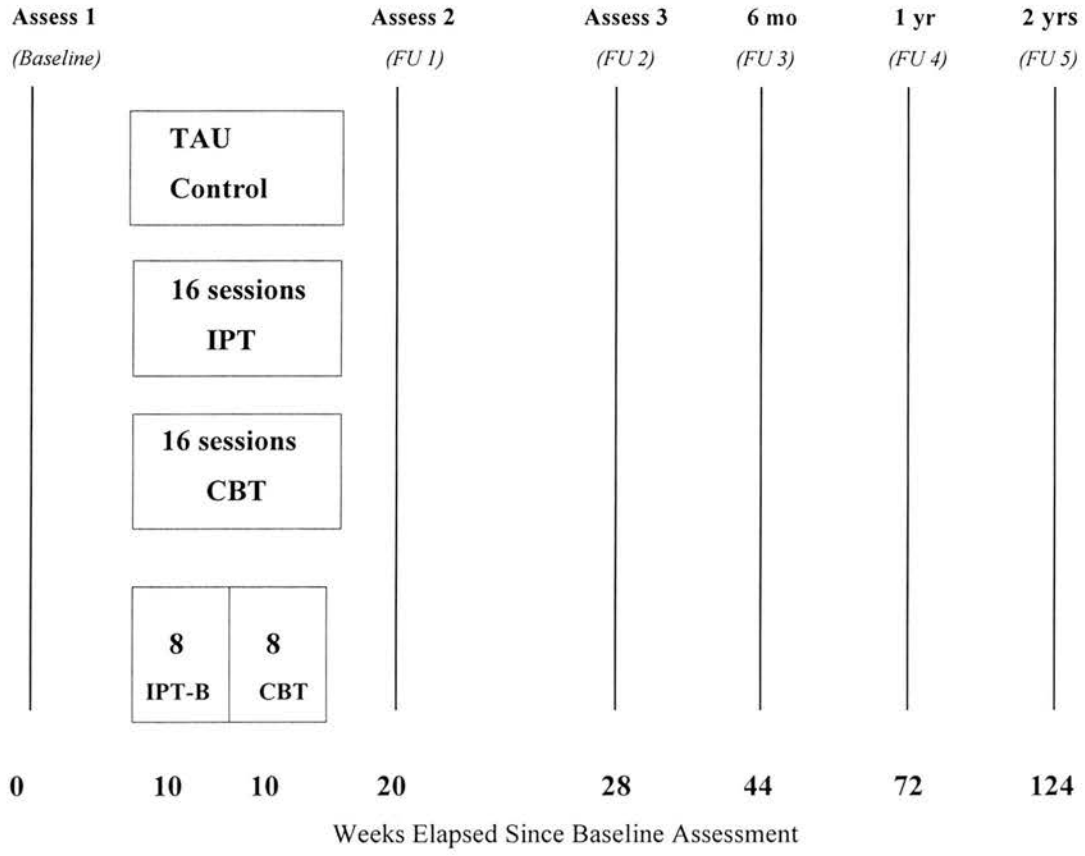


Figure 6.0: Future Comparative Psychotherapy Trial Incorporating IPT-B

Elkin (1999) has argued that outcome research needs to provide critical information about the therapists carrying out the treatment including the nature of the overall therapist sample, variability in therapist efficacy, therapist characteristics, training and supervision, and adherence and competence in carrying out the treatment.

It is also recommended that in the future the IPT-B manual (IPT-B) could be adapted to two forms: (1) Clinician IPT-B manual; (2) Patient IPT-B manual. The **patient** manual could be sent out prior to treatment as is currently occurring in a study in Melbourne, Australia whereby the Patient Guide with monitoring forms (Weissman, 1995) is sent to the patient before treatment begins in order to maximise the efficiency of therapist/patient contact; this would appear to make sense given the time limited nature of the IPT-B. Indeed, the design currently being considered is to examine the effectiveness of Guided CBT (using Mind Over Mood, Greenberger and Padesky, 1995) versus Guided IPT, using both 16 and 8 session protocols.

Blatt *et al.* (2000) suggest that the evaluation of broader life functioning and the meaning and value that treatment has for the patient in a variety of areas will be important in the future. They suggest that the findings may identify some of the mechanisms that could delay or prevent relapse or suggest a possible sequence to therapeutic change. Symptom reduction may be an important first step in therapeutic change but equally important may be the subsequent consolidation of feeling more able to cope with life situations and various potential depressogenic life stressors. Treatment should not only reduce symptoms but also the vulnerability to subsequent potentially disruptive experiences. Both of these dimensions need to be assessed when comparing the effects of different types of therapeutic intervention (Zuroff, Blatt, Sanislow, Bondi, and Pilkonis, 1999).

One final suggestion for future research is to address changes in clients' attachment styles over the course of the time-limited therapy; this would seem to be particularly relevant given that Attachment Theory, as developed by Bowlby (1969), provides a major theoretical source for understanding depression in an interpersonal context and is central to Interpersonal Psychotherapy for Depression. To date, this has not been attempted as an empirical investigation with patients as part of a programme of CBT or IPT but has recently been attempted with those undergoing time-limited dynamic psychotherapy (Travis, Binder, Bliwise, and Horne-Moyer, 2001) in which significant changes toward increased secure attachment were reported.

REFERENCES

Ablon, S.J., & Jones, E.E. (1999). Psychotherapy process in the National Institute of Mental health Treatment of Depression Collaborative Research Program, Journal of Consulting and Clinical Psychology, **67** (1) 64-75.

Addis, M.E. & Krasnow, A.D. (2000). A national survey of practicing psychologists' attitudes toward psychotherapy treatment manuals. Journal of Consulting and Clinical Psychology, **68** (2) 331-339.

Agosti, V., & Stewart, J. W. (1998). Social functioning and residual symptomatology among outpatients who responded to treatment and recovered from major depression. Journal of Affective Disorders, **47**, 207-210.

American Psychiatric Association. (1994). Diagnostic and statistical manual of mental disorders, 4th ed. [DSM-IV]. Washington,D. C.: American Psychiatric Association.

American Psychiatric Association. (2000). Practice guideline for major depressive disorder in adults. American Journal of Psychiatry, **150** (suppl, 4) 1-26.

Andrews, G., Sanderson, K., Slade, T. & Issakidis, C. (2000). Why does the burden of disease persist? Relating the burden of anxiety and depression to effectiveness of treatment. Bulletin of the World Health Organisation, **78,** 446-454.

Andrews, G. (2001). Should depression be managed as a chronic disease? British Medical Journal, **322** 419-421.

Angus, L., & Gillies, L.A. (1994). Counselling the borderline client: an interpersonal approach. Canadian Journal of Counselling, **28**, 69-82.

Arieti, S., & Bemporad, J. (1978). Severe and mild depression: the psychotherapeutic approach. New York: Basic Books.

Barlow, D.H. & Hersen, M. (1984). Single case experimental designs: Strategies for studying behaviour change. (2nd edn.). Oxford: Pergamon.

Beck, A.T., Ward, C.H., Mendelsohn, M., Mock, J., & Erbaugh, J. (1961). An inventory for measuring depression. Archives of General Psychiatry **4**, 561-571.

Beck, A.T., Steer, R.A. & Brown, G.K. (1996). Beck Depression Inventory-II. The Psychological Corporation, Harcourt Brace & Company, San Antonio.

Beck, A.T., Rush, A.J., Shaw, B.F., & Emery, G. (1979). Cognitive therapy of depression. New York:Guilford Press.

Becker, J. (1974). Depression: theory and research: New York: Wiley.

Blatt, S.J., Zuroff, D.C., Bondi, C.M., & Sanislow, C.A. (2000). Short- and long- term effects of medication and psychotherapy in the brief treatment of depression: Further analysis of data from the NIMH TDCRP. Psychotherapy Research, **10** (2), 215-234.

Blazer, D.G., Kessler, R.C., McGonagle, K.A., & Swartz, M.S. (1994). The prevalence and distribution of major depression in a national community sample: The national comorbidity survey. American Journal of Psychiatry, **151**: 979-986.

Bohart, A.D., O'Hara, M., & Leitner, L.M. (1998). Empirically validated treatments: Disenfranchisement of humanistic and other psychotherapies. Psychotherapy Research, **8**, 141-157.

Bowlby, J. (1969). Attachment. New York: Basic Books.

Bowlby, J. (1977). The making and breaking of affectional bonds: I. Aetiology and psychopathology in the light of attachment theory. British Journal of Psychiatry, **130:** 201-210.

Bowlby, J. (1982). Attachment, 2nd edition of vol.1 of Attachment and loss London: Hogarth Press.

Bowlby, J. (1988). A secure base: clinical applications of attachment theory. Routledge, London.

Brewin, C.R., & Bradley, C. (1989). Patient preferences and randomised controlled trials. British Medical Journal, **233**, 313-315.

Briscoe, C.W., & Smith, J.B. (1973). Depression and marital turmoil. Archives of General Psychiatry, **28:** 811-817.

British Medical Association. (2002).British National Formulary. **43.**

Brown, G.W., & Harris, T.O. (1978). Social origins of depression: A study of psychiatric disorder in women. London: Tavistock.

Brown, G.W., & Harris, T.O. (1989). Life events and illness. New York: Guilford Press.

Brown, G.W., & Harris, T.O., & Copeland, J.R. (1977). Depression and loss, British Journal of Psychiatry, **130**, 1-18.

Brown, G.W., Harris, T.O., & Hepworth, C. (1994). Life events and endogenous depression: a puzzle reexamined. Archives of General Psychiatry , **51**, 525-534.

Brown, C., Schulberg, H.C., Madonia, M.J., Shear, M.K. & Houck, P.R. (1996). Treatment outcomes for primary care patients with major depression and lifetime anxiety disorders. American Journal of Psychiatry, **153**, 1293-1299.

Brown, C., Schulberg, H.C., & Prigerson, H.G. (2000). Factors associated with symptomatic improvement and recovery from major depression in primary care patients. General Hospital Psychiatry, **22**, 242-250.

Brugha, T.S. (1995). Social support and psychiatric disorder: Research findings and guidelines for clinical practice. Cambridge University Press, Cambridge.

Brugha, T., Bebbington, P., MacCarthy, B., Sturt, E., Wykes, T., & Potter, J. (1990). Gender, social support and recovery from depressive disorders: a prospective clinical study. Psychological Medicine, **20**, 147-156.

Carroll, K.M., Rounsaville, B.J., & Gawin, F.H. (1991). A comparative trial of psychotherapies for ambulatory cocaine abusers: Relapse prevention and interpersonal psychotherapy. American Journal of Drug and Alcohol Abuse, **17**, 229-247.

Chambless, D.L., Baker, M., Baucom, D.H., Beutler, L.E., Calhoun, K.S. (1998). Update on empirically validated therapies, II. Clinical Psychology, **51** (1), 3-16.

Chambless, D.L., and Ollendick, T.H. (2001). Empirically supported psychological interventions: Controversies and evidence. Annual Review of Psychology, **52**, 685-717.

Chodoff, P. (1970). The core problem in depression. In J. Masserman (Ed.), Science and Psychoanalysis.Vol 17: New York: Grune and Stratton.

Christopoulos, K.A. (2001). The sick role in literature and society. Journal of American Medical Association, **285** (1) 93.

Clark-Carter, D. (1997). Doing quantitative psychological research. Psychological Press.

Cohen, M. B., Baker, G., Cohen, R.A., Fromm-Reichmann, F., & Weigert, E.A. (1954). An intensive study of twelve cases of manic depressive psychoses. Psychiatry, **17**, 103-137.

Cohen, J. (1988). Statistical power analysis for the behavioural sciences (2^{nd}edn.,) Hillsdale, NJ: Erlbaum.

Cohen, J. (1990). Things I have learned (so far). American Psychologist, **45**, 1304-1312.

Coryell, W., Endicott, J., & Keller, M. (1990). Outcome of patients with chronic affective disorder: a five year follow up. American Journal of Psychiatry, **147,** 1627-1633.

Dar, R., Serlin, R.C., and Omer, H. (1994). Misuse of statistical tests in three decades of psychotherapy research. Journal of Consulting and Clinical Psychology, **62**, 75-82.

Davanloo, H. (1978). Basic principles and techniques in short-term dynamic psychotherapy. New York: Spectrum.

DeRubeis, R.J., & Crits-Christoph, P. (1998). Empirically supported individual and group psychological treatments for adult mental disorders. Journal of Consulting and Clinical Psychology, **66** (1), 37-52.

DeRubeis, R.J., Gelfand, L.A., Tang, T.Z., & Simons, A.D. (1999). Medication versus cognitive behaviour therapy for severely depressed outpatients: Mega-analysis of four randomised comparisons. American Journal of Psychiatry, **156**, 1007-1013.

Department of Health (2001). Treatment choice in psychological therapies and counselling: Evidence based clinical practice guideline. London.

DiMascio,A., Weissman, M.M., Prusoff, B.A., Neu, C., Zwilling, M., & Klerman, G.L. (1979). Differential symptom reduction by drugs and psychotherapy in acute depression. Archives of General Psychiatry, **36**, 1450-1456.

Dohrenwend, B.S., Krasnoff, L., Askenasy, A.R. & Dohrenwend, B.P. (1978). Exemplification of a method for scaling life events: the PERI life events scale. Journal of Health and Social Behaviour, **19**, 205-229.

Drummond, M.F., O'Brien, B., Stoddart, G.L. & Torrance, G.L. (1997). Method for the economic evaluation of health care programmes. Oxford University Press.

Eckert, P.A. (1993). Acceleration of change: Catalysts in brief therapy. Clinical Psychology Review, **13,** 241-253.

Elliot, R., & Wexler, M.M. (1994). Measuring the impact of sessions in process-experiential therapy of depression: The Session Impacts Scale. Journal of Counselling Psychology, **41**, 166-174.

Elkin, I., Shea, M.T., Watkins, J.T., Imber, S.D., Sotsky, S.M., Collins, J.F., Glass, D.R., Pilkonis, P.A., Leber, W.R., Docherty, J.P., Fiester, S.J., & Parloff, M.B. (1989). National Institute of Mental Health Treatment of Depression Collaborative Research Program: General effectiveness of treatments. Archives of General Psychiatry, **46,** 971-982.

Elkin, I. (1994). The NIMH Treatment of Depression Collaborative Research Program: Where we began and where we are. In A.E. Bergin & S.L. Garfield (eds.)., Handbook of psychotherapy and behaviour change. (4th ed., 143-289). New York: Wiley.

Elkin, I., Parloff, M.B., Hadley, S.W., & Autry, J.H. (1985). NIMH Treatment of Depression Collaborative Research Programme: Background and research plan. Archives of General Psychiatry, **42**, 305-316.

Ezquiaga, E., Garcia, A., Bravo, F., & Pallares, T. (1998). Factors associated with outcome in major depression: a 6-month prospective study. Social Psychiatry Psychiatric Epidemiology, **33**, 552-557.

Fairburn, C.G. (1998). Eating disorders: Bulimia and anorexia nervosa. In Weissman, M.M., Markowitz, J.C. & Klerman, G.L. Comprehensive guide to interpersonal psychotherapy, 317-328. Basic Books, New York.

Fairburn, C.G., Jones, R., Peveler, R.C., Carr, S.J., Solomon, R.A., O'Connor, M.E., Burton, J., & Hope, R.A. (1991). Three psychological treatments for bulimia nervosa. Archives of General Psychiatry, **48,** 463-469.

Fairburn, C.G., Jones, R., Peveler, R.C., (1993). Psychotherapy and bulimia nervosa: the longer term effects of interpersonal psychotherapy, behaviour therapy, and cognitive behaviour therapy. Archives of General Psychiatry, **50**, 419-428.

Fairburn, C.G. (1993). Interpersonal psychotherapy for bulimia nervosa. In G.L. Klerman and M.M. Weissman (Eds.) New applications of interpersonal psychotherapy. Washington D.C.: American Psychiatric Press.

Fairburn, C.G., Norman, P.A., & Welch, S.L. (1995). A prospective study of outcome in bulimia nervosa and the long-term effects of three psychological treatments. Archives of General Psychiatry, **52**, 304-312.

Fava, G.A., Kellner, R., Munari, F., & Pavan, L. (1982). The Hamilton depression rating scale in normals and depressives. Acta Psychiatrica Scandinavica, *66,* 26-32.

First, M.B., Spitzer, R.L., Gibbon, M., and Williams, J.B. (1997). User's guide for the structured clinical interview for DSM-IV Axis I disorders: Clinician version (SCID-CV). Washington, DC, American Psychiatric Press.

Foley, D. (1990). Conjoint treatment for depressed patients with marital disputes (IPT-CM). In M.M. Weissman., J.C. Markowitz., & G.L. Klerman. Comprehensive guide to interpersonal psychotherapy, 223-266. Basic Books, New York.

Fonagy, P. (1999). Achieving evidence-based psychotherapy practice: a psychodynamic perspective on the general acceptance of treatment manuals. Clinical Psychologist: Science and Practice, **6**, 442-444.

Fletcher, R.H., Fletcher, S.W., & Wagner, E.H.W. (1988). Clinical epidemiology: The essentials. London: Williams and Wilkins.

Frank, J.D. (1973). Persuasion and healing: a comparative study of psychotherapy. Baltimore: Johns Hopkins University Press.

Frank, E. (1991). Interpersonal psychotherapy as a maintenance treatment for patients with recurrent depression. Psychotherapy, **28,** 259-266.

Frank, E., Kupfer, D.J., Perel, J.M., Cornes, C., Jarrett, D.B., Mallinger, A.G., Thase, M.E., McEachran, A.B. & Grochocinski, V.J. (1990). Three-year outcomes for maintenance therapies in recurrent depression. Archives of General Psychiatry, **47**, 1093-1099.

Frank, E., Kupfer, D.J., Wagner, E.F., McEachran, A.B., & Cornes, C. (1991). Efficacy of interpersonal psychotherapy as a maintenance treatment of recurrent depression: Contributing factors. Archives of General Psychiatry, **48** 1053-1059.

Frank, E., Anderson, B., Reynolds, C.F., Rietnour, A., & Kupfer, D.J. (1994). Life events and the Research Diagnostic Criteria endogenous type. Archives of General Psychiatry, **51**, 519-524.

Frank, E and Spanier, C. (1995). Interpersonal Psychotherapy for Depression: Overview, Clinical Efficacy, and Future Direction. Clinical Psychology: Science and Practice. **2**, 349-369.

Fromm-Reichmann, F. (1960). Principles of intensive psychotherapy. Chicago: Phoenix Books.

Gaffan, E.A., Tsaousis, I., & Kemp-Wheeler, S.M. (1995). Researcher alliance and meta-analysis: The case of cognitive therapy for depression. Journal of Consulting and Clinical Psychology, **63**, 966-980.

Garfield, S.L. (1996). Some problems associated with "validated" forms of psychotherapy. Clinical Psychology: Science and Practice, **3**, 241-244.

George, L.K., Blazer, B.G., Hughes, D.C., & Fowler, N. (1989). Social support and the outcome of major depression. British Journal of Psychiatry, **154,** 478-485.

Gibbons, R.D., Hedeker, D., Elkin, I., Waternaux, C., Kraemer, H.C., Greenhouse, J.B., Shea, T., Imber, S.D., Sotsky, S.M., & Watkins, J.T. (1993). Some conceptual and

statistical issues in analysis of longitudinal psychiatric data: Application to the NIMH Treatment of Depression Collaborative Research Program dataset. Archives of General Psychiatry, **50**, 739-750.

Gladis, M.M., Gosch, E.A., Dishuk, N.M., Crits-Christoph, P. (1999). Quality of life: Expanding the scope of clinical significance. Journal of Consulting and Clinical Psychology, **67,** 320-331.

Gore, S.M. (1981a). Assessing clinical trials - record sheets. British Medical Journal, ***283,*** 296-298.

Graham, B.J. & McGregor K. (1997). What does a GP consultation cost? British Journal of General Practice, **47,** 170-172.

Greenberger, D. & Padesky, C.A. (1995). Mind over mood: Change how you feel by changing the way you think. Guilford Press: New York.

Greenhalgh, T. (1997). How to read a paper: Statistics for the non-statistician. II: "Significant" relations and their pitfalls. British Medical Journal, **315**, 422-425.

Hamilton, M. (1960). A rating scale for depression. Journal of Neurology, Neurosurgery and Psychiatry, **23,** 56-62.

Harris, T. (2001). Recent developments in understanding the psychosocial aspects of depression. British Medical Bulletin, **57**, 17-32.

Hedlung, J.L., and Vieweg, B.W. (1979). The Hamilton rating scale for depression: A comprehensive review. Journal of Operational Psychology, **10**, 149-165.

Henderson, S., Byrne, D.G., & Duncan-Jones, P. (1981). Neurosis and the social environment. Sydney: Academic Press.

Hewitt, P.L., Flett, G.L., Turnbull-Donovan, W., & Mikail, S. (1991). The Multidimensional Perfectionism Scale: Reliability, validity, and psychometric properties in psychiatric samples. Psychological Assessment: A Journal of Consulting and Clinical Psychology, **3,** 464-468.

Hinchliffe, M., Hooper, D., & Roberts, F.J. (1978). The melancholy marriage. New York: Wiley.

Hsu, L.M. (1989). Reliable changes in psychotherapy: taking into account regression toward the mean. Behavioural Assessment, **11**, 459-467.

Hughes, P. (1999). Dynamic psychotherapy explained. Radcliffe Medical Press Ltd, Oxon.

Information & Statistics Division (2001). Scottish health service costs , Edinburgh: UK.

Jacobson, N.S., and Truax, P. (1991). Clinical Significance: A statistical approach to defining meaningful change in psychotherapy research. Journal of Consulting and Clinical Psychology, **59**, 12-19.

Jarrett, R.B., & Rush, A.J. (1994). Short term psychotherapy of depressive disorders: Current status and future directions. Psychiatry, **57**, 15-132.

Kazdin, A.E. (1981). Drawing valid inferences from case studies. Journal of Consulting and Clinical Psychology, **49**, 183-192.

Keitner, G.J., Ryan, C.E., Miller, I.W., Kohn, R., & Epstein, N.B. (1991). 12-month outcome of patients with depression and comorbid psychiatric or medical illness (Compound Depression). American Journal of Psychiatry, **148,** 345-350.

Kendall, P.C., Chu, B., Gifford, A., Hayes, C., & Nauta, M. (1998). Breathing life into a manual: flexibility and creativity with manual0based treatments. Cognitive Behavioural Practice**, 5**, 177-198.

Klein, D.F., & Ross, D.C. (1993). Reanalysis of the National Institute of Mental Health Treatment of Depression Collaborative Research Program general effectiveness report. Neuropsychopharmacology, **8**, 241-251.

Klerman, G.L., DiMascio, A., Weissman, M.M., Prusoff, B.A., & Paykel, E.S. (1974). Treatment of depression by drugs and psychotherapy. American Journal of Psychiatry, **131:** 186-191.

Klerman, G.L., Weissman, M.M., Rounsaville, B.J., & Chevron (1984). Interpersonal psychotherapy of depression. New York: Basic Books.

Klerman, G.L., Budman, S., Berwick, D., Weissman, M.M., Damico-White, J., Demby, A. & Feldstein, M. (1987). Efficacy of a brief psychosocial intervention for symptoms of stress and distress among patients in primary care. Medical Care, **25**, 1078-1088.

Klerman, G.L. & Weissman, M.M. (1993). New applications of interpersonal psychotherapy. Washington D.C., American Psychiatric Press.

Kung, W.W., & Elkin, I. (2000). Marital adjustment as a predictor of outcome in individual treatment of depression. Psychotherapy Research. **10**(3), 267-278.

Lambert, M.J., Shapiro, D.A., & Bergin, A.E. (1986). The effectiveness of psychotherapy. In S.L. Garfield & A.E. Bergin (Eds.), Handbook of psychotherapy and behaviour change (3r^{d}ed., 157-211). New York: Wiley.

Lazarus, R.S. (1984). Stress, appraisal, and coping. New York: Springer.

Lipsitz. J.D., Fyer, A.J., Markowitz, J.C. & Cherry, S. (in press). An open trial of interpersonal psychotherapy for social phobia. American Journal of Psychiatry.

Malan, D.H. (1976). The frontier of brief psychotherapy: An example of the convergence of research and clinical practice. New York: Plenum.

Mann, J. & Goldman, R. (1982). A casebook in time-limited psychotherapy. New York: McGraw-Hill.

Markowitz, J.C., Klerman, G.L., Perry, S.W. (1993). Interpersonal therapy for depressed HIV-seropositive patients. In G.L. Klerman and M.M. Weissman (Eds.). New

applications of interpersonal psychotherapy. Washington D.C.: American Psychiatric Press.

Markowitz, J.C. (1994). Psychotherapy of dysthymia. American Journal of Psychiatry, **151**, 1114-1121.

Markowitz, J.C. (1998). Interpersonal psychotherapy for dysthymic disorder. Washington, D.C.: American Psychiatric Press.

Margison, F. and McGrath, G. (1989). Research in psychotherapy. In C. Freeman and P.Tyrer (Eds.), Research methods in psychiatry: A beginner's guide. Gaskell, London.

McKenzie, J., Bulik, C. McKenzie, J.M., Luty, S.E., & Jordan, J. (2000). Interpersonal psychotherapy for anorexia nervosa. International Journal of Eating Disorders. **27**, 125-139.

Meyer, A.(1951). The life chart and the obligation of specifying positive data in psychopathological diagnosis. In: Winters, E.E. (Ed.), Medical teaching. The collected papers of Adolf Meyer, Vol. III. The John Hopkins Press, Baltimore, 52-56.

Meyer, A.(1957). Psychobiology: A science of man. Springfield,Ill.: Charles C. Thomas

Monroe, S.M., Kupfer, D.J., & Frank, E. (1992). Life stress and treatment course of recurrent depression: 1. Response during index episode. Journal of Consulting and Clinical Psychology, **60**, 718-724.

Moreau, D., Mufson, L., Weissman, M.M. & Klerman, G.L. (1991). Interpersonal psychotherapy for adolescent depression: Description of modification and preliminary application. Journal of American Academic Child & Adolescent Psychiatry, **30**, 642-651.

Morley, S. (1989). Single case research. In G. Parry & F.N. Watts (Eds.), Behavioural and mental health research: A handbook of skills and methods. London. Lawrence Erlbaum Associates.

Mufson, L., Moreau, D., Weissman, M.M., Klerman, G.L. (1993). Interpersonal therapy for depressed adolescents. New York: Guilford Press.

Mufson, L., Weissman, M.M., Moreau, D., & Garfinkel, R. (1999). Efficacy of interpersonal psychotherapy for depressed adolescents. Archives of General Psychiatry, **56,** 573-579.

Murray, C.J. & Lopez, A.D. (1997) Alternate projections of mortality and disability by cause 1990-2020: global burden of disease study. Lancet, **349,** 1498-1504.

Nelson, R.O. (1981). Realistic dependent measures for clinical use. Journal of Consulting and Clinical Psychology, **49,** 168-182.

Neurolink (2002). Practical solutions for anxiety and depression: Depression guidelines, recognition and management in general practice. (2n^{d} Edn). Wyeth Laboratories.

Oakes, M. (1986). Statistical inference: A commentary for the social and behavioural sciences. New York: Wiley.

O'Carroll, R.E., Smith, K., Couston, M., Cossar, J.A., & Hayes, P.C. (2000). A comparison of the WHOQOL-100 and the WHOQOL-BREF in detecting change in quality of life following liver transplantation. Quality of Life Research, **9,** 121-124.

Ogles, B.M., Lambert, M.J., Weight, D.G., & Payne, I.R. (1990). Agoraphobia outcome measurement: A review and meta-analysis. Psychological Assessment, **2**, 317-325.

Ogles, B.M., Lambert, M.J., & Sawyer, J.D. (1995). Clinical significance of the national institute of mental health treatment of depression collaborative research programme data. Journal of Consulting and Clinical Psychology, **63** (2), 321-326.

Parker, G. (1978). The bonds of depression. Sydney: Angus and Robertson Publishers.

Parsons, T. (1951). The social system. Free Press, Glencoe, IL.

Paykel, E.S., Myers, J.K., Dienelt, M.N., Klerman, G.L., Lindenthal, J.J., & Pepper, M.P. (1969). Life events and depression: A controlled study. Archives of General Psychiatry, **21**, 753-760.

Paykel, E.S., Rao, B.M., & Taylor, C.N. (1984). Life stress and symptom pattern in out-patient depression. Psychological Medicine, **14,** 559-568.

Paykel, E.S. (1997). The Interview for Recent Life Events. Psychological Medicine, **27**, 301-310.

Paykel, E.S. (2001). The evolution of life events research in psychiatry. Journal of Affective Disorders, **62**, 141-149.

Patience, D., McGuire, R., Scott, A., & Freeman, C. (1995). The Edinburgh primary care depression study: personality disorder and outcome. British Journal of Psychiatry, **167**, 324-330.

Pearlin, L.I., & Lieberman, M.A. 91979). Social sources of emotional distress. In R.Simmons (Ed.), Research in Community and Mental Health (Vol 1:217-248). Greenwich, CT: JAI Press.

Pilkonis, P.A., Imber, S.D., Lewis, P., and Rubinsky, P. (1984). A comparative outcome study of individual, group and conjoint psychotherapy. Archives of General Psychiatry, **41**, 431-437.

Power, M. & Champion, L. and Aris, S.J. (1988). The development of a measure of social support: The Significant Others (SOS) Scale. British Journal of Clinical Psychology, **27,** 349-358.

Ramana, R., Paykel, E., Cooper, Z., Hayhurst, H., Saxty, M., & Surtees, P. (1995). Remission and relapse in major depression: a two year prospective follow up study. Psychological Medicine, **25,** 1161-1170.

Reynaert, C., Janne, P., Vause, M., Zdanowicz, N., & Lejeune, D. (1995). Clinical trials of antidepressants: the hidden face: where locus of control appears to play a key role in depression outcome. Psychoharmacology, **119**, 449-454.

Reynolds, S., Stiles, W.B., Barkham, M., Shapiro, D.A., Hardy, G.E. & Rees, A. (1996). Acceleration of changes in session impact during contrasting time-limited psychotherapies. Journal of Consulting and Clinical psychology, **64,** 577-586.

Reynolds, C.F., III., Frank, E., Perel, J.M., Imber, S.D., Cornes, C., Miller, M.D., Mazumdar, S., Houck, P.R., Dew, M.A., Stack, J.A., Pollock, B.G., & Kupfer, D.J. (1999). Nortriptyline and interpersonal psychotherapy as maintenance therapies for recurrent major depression: A randomised controlled trial in patients older than fifty-nine years. Journal of American Medical Association, **281**, 39-45.

Robbins, D.R., Alessi, N.E., & Colfer, M.V. (1985). Use of the Hamilton rating scale for depression and the Carroll self-rating scale in adolescents. Psychiatry Research, **14**, 123-129.

Roth, A., & Fonagy, P. (1996). What works for whom? A critical review of psychotherapy. New York: Guilford Press.

Rounsaville, B.J., Weissman, M.M., Prusoff, B.A., and Hercet-Barob, R. (1979). Marital disputes and treatment outcome in depressed women. Comprehensive Psychiatry, **20,** 483-490.

Rounsaville, B.J., Prusoff, B.A., and Weissman, M.M. (1980). The course of marital disputes in depressed women: A 48-month follow-up study. Comprehensive Psychiatry, **21,** 111-118.

Rounsaville, B.J., Glazer, W., Wilber, C.H., Weissman, M.M., & Kleber, H.D. (1983). Short-term interpersonal psychotherapy in methadone maintained opiate addicts. Archives of General Psychiatry, **40**, 629-636.

Rounsaville, B.J., Chevron, E.S., Weissman, M.M., Prusoff, B.A. & Frank, E. (1986). Training therapists to perform psychotherapy in clinical trials. Comprehensive Psychiatry, **4**, 364-371.

Rush, A.J., & Thase, M.E. (1999). Psychotherapies for depressive disorders: A review. In M.Maj & N. Sartorius (Eds.), WPA Series: Evidence and experience in psychiatry: Volume 1: Depressive disorders, 161-206. Chichester, UK: Wiley.

Rutter, M. (1972). Maternal deprivation reconsidered. Journal of Psychosomatic Research, **16,** 241-250.

Rutter, M. (1995). Clinical implications of attachment concepts: retrospect and prospect. Journal of Child Psychology and Psychiatry, **36** (4), 549-571.

Saunders, S.M., Howard, K.I., & Newman, F.L. (1988). Evaluating the clinical significance of treatment effects: Norms and normality. Behavioural Assessment**, 10**, 207-218.

Seligman, M.E. (1996). The effectiveness of psychotherapy. American Psychologist, **50,** 965-974.

Shapiro, D.A. (1989). Outcome research. In G.Parry & F.Watts (Eds.), Behavioural and mental health research A handbook of skills and methods. Hove: Lawrence Erlbaum Associates.

Shapiro, D.A., Barkham, M., Hardy, G.E., & Morrison, L.A. (1990). The second Sheffield psychotherapy project: Rationale, design and preliminary outcome data. British Journal of Medical Psychology, **63,** 97-108.

Shapiro, D.A., Barkham, M., Rees, A., Hardy, G.E., Reynolds, S. & Startup M. (1994). Effects of treatment duration and severity of depression on the effectiveness of cognitive-behavioural and psychodynamic-interpersonal psychotherapy. Journal of Consulting and Clinical Psychology, **62,** 522-533.

Shaw, B.F., Olmstead, M., Dobson, K.S., Sotsky, S.M., Elkin, I., Yamaguchi, J., Vallis, T.M., Lowery, A., Watkins, J.T., & Imber, S.D. (1999). Therapist competence ratings in relation to clinical outcome in cognitive therapy of depression. Journal of Consulting and Clinical Psychology, **67**, 837-846.

Shea, M.T., Elkin, I., Imber, S.D., Sotsky, S.M., Watkins, J.T., Collins, J.F., Pilkonis, P.A., Beckham, E., Glass, D.R., Dolan, R.T., & Parloff, M.B. (1992). Course of depressive symptoms over follow-up: Findings from the National Institute of Mental health Treatment for Depression Collaborative Research Program. Archives of General Psychiatry, **49**, 782-794.

Shea, M.T., Widiger, T.A., & Klein, M.H. (1993). Comorbidity of personality disorders and depression: implications for treatment. Journal of Consulting and Clinical Psychology, **60**, 857-868.

Sifneos, P.E. (1979). Short term dynamic psychotherapy: Evaluation and technique. New York: Plenum.

Simons, A.D., Lustman, P.J., & Wetzel, R.D. (1985). Predicting responses to cognitive therapy of depression: the role of learned resourcefulness. Cognitive Therapy and Research, **9**, 79-89.

Smith, A.L. & Weissman, M.M. (1992). Epideiology. In E.S. Paykel (Ed.), Handbook of affective disorders, 111-129. New York: Guilford.

Sotsky, S.M., Glass, D.R., Shea, T., Pilkonis, P.A., Collins, J.J., Elkin, I., Watkins, J.T., Imber, S.D., Leber, W.R., Moyer, J., & Oliveri, M.E. (1991). Patient predictors of response to psychotherapy and pharmacotherapy: Findings in the NIMH treatment of depression collaborative research program. American Journal of Psychiatry, **148**, 997-1008.

Sotsky, S.M. (1997). Pharmacotherapy and psychotherapy response in atypical depression: Findings from the NIMH treatment of depression collaborative research program. Paper presented as part of Symposium 73 at the American Psychiatric Association 150th Annual Meeting, San Diego, CA.

Steiner, M., Browne, G., Roberts, J., Gafni, A., Byrne, C., Bell, B., & Dunn, E. (1998). Sertraline and IPT in dysthymia: One-year follow up. In M.M. Weissman., J.C. Markowitz., & G.L. Klerman. Comprehensive guide to interpersonal psychotherapy, 223-266. Basic Books, New York.

Sterne, J., and Smith, G.D. (2001). Sifting the evidence - what's wrong with significance tests? British Medical Journal, **322**, 226-231.

Stewart, J.W., Garfinkel, R., Nunes, E.V., Donovan, S., & Klein, D.F. (1998). Atypical features and treatment response in the national institute of mental health treatment of depression collaborative research program. Journal of Clinical Psychopharmacology, **18** (6), 429-434.

Stewart, L.A. & Parmar, M.K. (1996). Bias in the analysis and reporting of randomised controlled trials. International Journal of Health technology Assessment, **12**, 264-275.

Stone, A.A., Shiffman, S., Schwartz, J.E., Broderick, J.E., & Hufford, M.R. (2002). Patients non-compliance with paper diaries. British Medical Journal, **342**, 1193-1194

Stuart, S. (1999). Interpersonal psychotherapy for postpartum depression. In L. Miller (Ed.), Postpartum psychiatric disorders. Washington, D.C.: American Psychiatric Press, 143-162.

Stuart, S. & Cole, V. (1996). Treatment of depression following myocardial infarction with interpersonal psychotherapy. Annals. of Clinical Psychiatry, **8,** 203-206.

Sullivan, H.S. (1953). The interpersonal theory of psychiatry. New York:Norton.

Travis, L.A., Binder, J.L., Bliwise, N.C., & Horne-Moyer, H.L. (2001). Changes in clients' attachment styles over the course of time-limited dynamic psychotherapy. Psychotherapy, **38**, 149-159.

Vallejo, J., Gasto, C., Catalan, R., Bulbena, A., & Menchon, J. (1991). Predictors of antidepressant treatment outcome in melancholia: Psychosocial, clinical and biological indicators. Journal of Affective Disorders, **20**, 151-162.

Veiel, H.O., Kuhner, C., Brill, G., & Ihle, W. (1992). Psychosocial correlates of clinical depression after psychiatric inpatient treatment: methodological issues and baseline differences between recovered and non-recovered patients. Psychological Medicine, **22**, 415-427.

Wampold, B.E. (1997). Methodological problems in identifying efficacious psychotherapies. Psychotherapy Research, **7**, 21-43.

Warren, W.L. (1994). Revised Hamilton rating scale for depression (RHRSD): Manual. Western Psychological Services, Los Angeles, California.

Watkins, J.T., Leber, W.R., Imber, S.D., Collins, J.R., Elkin, I., Pilkonis, P.A., Sotsky, S.M., Shea, M.T., & Glass, D.R. (1993). NIMH treatment of depression collaborative research program: temporal course of change of depression. Journal of Consulting and Clinical Psychology, **61**, 858-864.

Weissman, M.M. & Paykel, E.S. (1974). The depressed women: A study of social relationships. Chicago: University of Chicago Press.

Weissman, M.M., Klerman, G.L., Paykel, E.S., Prusoff, B.A., & Hanson, B. (1974). Treatment effects on the social adjustment of depressed women. Archives of General Psychiatry, **30**, 771-778.

Weissman, M.M., Prusoff, B.A., DiMascio, A., Neu, C. Goklaney, M., & Klerman, G.L. (1979). The efficacy of drugs and psychotherapy in the treatment of acute depressive episodes. American Journal of Psychiatry, **136,** 555-558.

Weissman, M.M., Klerman, G.L., Prusoff, B.A., Sholomskas, D., & Padin, N. (1981). Depressed outpatients one year after treatment with drugs and/or interpersonal psychotherapy (IPT). Archives of General Psychiatry, **38**, 51-55.

Weissman, M.M., and Klerman, G.L. (1988). Interpersonal Counselling (IPC) for stress and distress in primary care settings. New York, New York State Psychiatric Institute.

Weissman, M.M. (1993). Interpersonal counselling for stress and distress in primary care settings. In G.L. Klerman and M.M. Weissman (Eds.) New applications of interpersonal psychotherapy. Washington D.C.: American Psychiatric Press.

Weissman, M.M. (1995). Mastering depression through interpersonal psychotherapy, and monitoring forms booklet. Psychological Corporation, Order Service Centre, P.O. Box 839954, San Antonio, Texas 78283-3954.

Weissman, M.M., Markowitz, J.C. & Klerman, G.L. (2000). Comprehensive guide to Interpersonal Psychotherapy. Basic Books, New York.

Wells, K.B., Stewart, A., Hays, R.D., Burnam, A., Rogers, W., Daniels, M., Berry, S., Greenfield, S., & Ware, J. (1989). The functioning and well-being of depressed patients. Journal of the American Medical Association, **262**, 914-919.

Wilfley, D.E., Agras, W.S., Telch, C.F., Rossiter, E.M., Schneider., J.A., Cole, A.G., Sifford, L.A., & Raeburn, S.D.(1993). Group cognitive-behavioural therapy and group interpersonal therapy for the nonpurging bulimic individual. Journal of Consulting and Clinical Psychology, **61** (2), 296-305.

Wilfley, D.E., Frank, M.A., Welch, R., Spurrell, E.B., & Rounsaville, B.J. (1998). Adapting Interpersonal Psychotherapy to a group format (IPT-G) for binge eating disorder: Toward a model for adapting empirically supported treatments. Psychotherapy Research, **8**, 379-391.

Wilson, G.T. (1998). Manual-based treatment and clinical practice. Clinical Psychologist: Science and Practice, **5**, 363-375.

Woody, G.E., McLellan, A.T., & Luborsky, L. (1984). Severity of psychiatric symptoms as a predictor of benefits from psychotherapy: the Veterans administration study. American Journal of Psychiatry, **141**, 1172-1177.

Woody, S.R., & Sanderson, W.C. (1998). Manuals for empirically supported treatments: 1998 update. Clinical Psychology, **51** (1), 17-21.

World Health Organisation: Programme on Mental Health (1996). World Health Organisation Quality of Life - WHOQOL-BREF. WHO-Geneva.

Zitman, F.G., Mennen, M.F., Griez, E., & Hooper, C. (1989). The different versions of the Hamilton Depression scale. In P.Bech & A. Coppen (Eds.), The Hamilton scale. Heidelberg: Springer.

Zlotnick, C.,Shea, M.T., Pilonis, P.A., Elkin, I., & Ryan, C. (1996). Gender, type of treatment, dysfunctional attitudes, social support, life events and depressive symptoms over naturalistic follow-up. American Journal of Psychiatry, **153**, 1021-1027.

Zuroff, D.C., Blatt, S.J., Sanislow, C.A., Bondi, C.M., & Pilkonis, P.A. (1999). Vulnerability to depression: re-examining stability and mood state dependence. Journal of Abnormal Psychology, **108,** 76-89.

Zuroff, D.C., Blatt, S.J., Sotsksy, S.M., Krupnick, J.L., Martin, D.J., Sanislow, C.A., & Simmens, S. (2000). Relation of therapeutic alliance and perfectionism to outcome in brief outpatient treatment of depression. Journal of Consulting and Clinical Psychology, **68**, (1), 114-124.

APPENDICES 1-14

DSM-IV DIAGNOSTIC CRITERIA FOR MAJOR DEPRESSIVE DISORDER

(American Psychiatric Association, 1994).

A. Five (or more) of the following symptoms have been present nearly every day during the same two-week period and represent a change from previous functioning: at least one of the symptoms is either (1) depressed mood or (2) loss of interest or pleasure

1. depressed mood most of the day, nearly every day, as indicated by either subjective report (e.g. feels sad or empty) or observation made by others (e.g. appears tearful)

2. markedly diminished interest or pleasure in all, or almost all, activities most of the day, nearly every day (as indicated by either subjective account or observation made by others)

3. significant weight loss when not dieting or weight gain (e.g. a change of more than 5% of body weight in a month), or decrease or increase in appetite nearly every day.

4. insomnia or hypersomnia nearly every day

5. psychomotor agitation or retardation nearly every day (observable by others, not merely subjective feelings of restlessness or being slowed down)

6. fatigue or loss of energy nearly every day

7. feelings of worthlessness or excessive or inappropriate guilt (which may be delusional) nearly every day (not merely self-reproach or guilt about being sick)

8. diminished ability to think or concentrate, or indecisiveness, nearly every day (either by subjective account or as observed by others)

9. recurrent thoughts of death (not just fear of dying), recurrent suicidal ideation without a specific plan, or a suicide attempt or a specific plan for committing suicide

B. The symptoms do not meet criteria for a Mixed Episode.

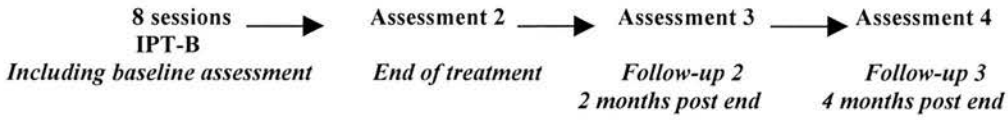
C. The symptoms cause clinically significant distress or impairment in social, occupational, or other important areas of functioning.

D. The symptoms are not due to the direct physiological effects of a substance (e.g., a drug of abuse, a medication) or a general medical condition (e.g., hypothyroidism).

E. The symptoms are nor better accounted for by Bereavement i.e., after the loss of a loved one, the symptoms persist for longer than 2 months or are characterised by marked functional impairment, morbid preoccupation and worthlessness, suicidal ideation, psychotic symptoms, or psychomotor retardation

APPENDIX 2.0 ILLUSTRATIVE CASE STUDIES IAN (IK) and LINDA (LN)

The following is a description of two individual cases, chosen as detailed illustrative examples of IPT-B as an intervention utilising the Role Transition focus area. Using the single case design, Ian, who received therapy (IPT-B) showed overall considerable improvement whereas Linda, who also received IPT-B did not show overall improvement, either subjectively or objectively. In both cases, there were 3 follow-up assessments, which enriched the quality of the data. The design for the two case studies was as follows:



2.1 PRESENTING PROBLEM/PATIENT DESCRIPTION OF IAN: *Successful Treatment*

Ian was a 53 year-old self-employed mechanic, who had separated from his second wife (DK) 6 months prior to presentation. Ian had 2 children from his first marriage of 25 years. He sought treatment as he recognised the symptoms of depression from an episode 10 years prior to presentation, coinciding with the time he separated from his first wife. Depressive symptoms were first reviewed with Ian. He complained of a clear onset of symptoms such as depressed mood, markedly diminished interest and pleasure in daily activities, feelings of worthlessness and excessive guilt, lack of energy, insomnia, diminished ability to concentrate and decreased appetite. Ian met DSM-IV criteria for MDD and had a Revised Hamilton Depressive Rating Scale score of 19, characterised as "major depression." Ian's symptoms were discussed with him at the first session when he was clear that the onset of depression had occurred at approximately the time of separation from his second wife.

2.11 Case Formulation for Ian

IPT Session 3: A Role Transition

The primary goal of the third session was to discuss a formulation with Ian, outline the treatment goals and reiterate how IPT-B is conducted. Ian's difficulties were formulated within a Role Transition Focus: making the transition from being part of a married couple to being single man again. Ian's symptoms of depression were conceptualised as being maintained by his difficulty in accepting the role change. We spent time exploring what was lost when Ian's second marriage ended and the unexpressed emotion which accompanied the transition. The goals of a role transition guided the treatment formulation and the therapeutic process, as such:

1. Facilitation of mourning and acceptance of the loss of the old role of husband and provider.
2. Helping Ian to regard the new role of single man, as more positive.
3. Helping Ian to restore self-esteem by developing a sense of mastery regarding the demands of the new role (Klerman *et al.* 1984).

Ian appeared to be extremely motivated to change and from the outset and appeared to be determined to improve. He took on board the model of therapy and suggestions made regarding asking others for help. Ian's symptoms gradually improved on a weekly basis (measured objectively using BDI-II); he was able to verbalise his needs and to prioritise his recovery. By the end of therapy, Ian was aware of times when it was acceptable to ask others for help; this was perhaps the single most important shift in Ian's thinking as a result of therapy. Initially, Ian would have perceived that to ask other people for help in any way

would have been evidence of *"weakness"* and therefore was to be avoided at all costs. Indeed, coming to therapy was an extremely difficult decision and process for Ian.

The focus of our work was maintained in the present and in the future, in terms of ways that Ian could manage his symptoms more effectively and ways to improve his social network. Indeed, it would appear that Ian had a wide and caring network of people whom he could call on to support him in many different ways, reflected in the objective measures of change, for example the Significant Others Scale (Power *et al.* 1988) and the WHOQOL (1996). Throughout treatment, Ian was periodically reminded of the number of remaining sessions and the 3 follow-up sessions (end of treatment; 2-month and 4-month follow-up). In IPT-B there is an explicit discussion of termination issues, as the prospect of ending therapy is perceived as being a time of **potential** mourning and therefore may be unsettling. The ending however is also viewed as an opportunity to model a "successful ending." With Ian, gains were attributed to him, progress was documented and confidence in dealing with future problems was reinforced. By the final session, Ian was doing considerably better, as is reflected in all the objective measures of change.

2.12 Summary for Ian

Ian presented to Primary Care with a clear onset of depressive symptoms, significant enough to reach a diagnosis of Major Depressive Disorder according to DSM-IV Criteria, the time of which coincided with the break up of his second marriage. The IPT-B model appeared to 'fit' with Ian's experience of depression and the time limited, focussed nature of our work together appeared to have a significant impact on Ian's interpersonal functioning and quality of life. As discussed earlier, the assignment of the "sick role" with the diagnosis of depression served to "normalise" Ian's experience and demonstrated to him that we were talking about the same "illness". It also demonstrated, at the outset, the possibilities for recovery and allowed the therapist to hold the positive stance advocated by the IPT model (Klerman *et al.* 1984).

2.2 PRESENTING PROBLEM/PATIENT DESCRIPTION OF LINDA: *Unsuccessful Treatment*

Linda was a 51 year-old, married mother of 2 adult females. She sought treatment as she felt that although she had had a *"lifetime of troubles"* she did not want to get any older and not be able *"to do things that* she *[I] wanted to do."* Linda complained of depressed mood, loss of appetite and energy, insomnia, inability to concentrate, feelings of worthlessness and *"feeling sick all the time."* Linda was unable to describe a clear onset of symptoms and according to DSM-IV criteria was diagnosed as having Major Depressive Disorder superimposed on Dysthymic Disorder. According to Linda, she had experienced problems since she was 7 years old and indeed was treated with psychiatric help from the age of 9-15 years. Linda left school at 15 years old and did not receive any further help until she was 40 years old, at which time she sought help for depressive symptoms; she was given therapeutic input by a clinical psychologist, which terminated when the psychologist left her post. At baseline assessment, Linda's Revised Hamilton Depressive Rating Scale score was 25, which is characterised as "major depression"; she denied any suicidal ideation.

2.21 Case Formulation

IPT Session 3: A Role Transition

The primary goal of the third session was exactly the same with Linda as it was with Ian, i.e to discuss the formulation, outline the treatment goals and reiterate how IPT-B is conducted. Linda's presenting problems were formulated as being a difficulty associated with making a transition from a lifetime of feeling unwell *("feeling sick all the time")* to feeling well. Linda's symptoms of depression were conceptualised as being maintained by her inability to accept a loss of the "sick role." We spent time exploring what a loss of the "sick role" would

mean to Linda and exploring *giving* Linda a "sick role" as part of IPT-B. The goals of the role transition guided the treatment formulation and the therapeutic process, as described earlier for Ian.

It became clear that Linda had learnt to adopt a "sick role" early on in life, as had her own mother. As time progressed, the "sick role" became more adaptive and actually served to help Linda to get her needs met as a young child. Linda continued into her adult life with the same role, which had served her well until she reached an age whereby it became increasingly clear that her "sick role" was actually stopping her from doing the things that she wanted to do. Linda discovered that those around her (family and friends) were becoming less inclined to legitimise her "sickness" as she was quite clearly not following the culturally determined conventions of being ill, such as trying to regain health as quickly as possible, or accepting help in overcoming the illness (Christopoulos, 2001). As she tried to lose her familiar role, she realised that she was unable to change. The process of trying to make that transition had become increasingly difficult and there was a great deal of failure associated with the concept of change for Linda. Although there were no clear precipitants to the current episode of depression, we formulated the precipitant as an increase in age associated with a fear that she would be unable to achieve some of her ambitions, however small they may seem. Our attention became focussed on the possibilities for the future in terms of making a transition to a life of not *"feeling sick"* and especially the meaning of the loss of the old role for Linda. By the final session of IPT-B, Linda's subjective and objective reports demonstrated no improvement in either the severity of the symptoms of depression or in the quality of her interpersonal relationships. The goals of IPT-B were not achieved with Linda by session 8 or by follow-up. It was hypothesised that Linda's attempts at engaging in therapy were indeed her attempts at trying to legitimise her familiar sick role, both for herself and her family, but also discovered that through that process, there was also the process of accepting help to overcome the depression.

2.22 Summary for Linda

Linda presented to Primary Care with a 2-year-plus period of Dysthymic Disorder with a superimposed Major Depressive Disorder (MDD). The presenting symptoms of depression began approximately one year prior to presentation and coincided with Linda's 50th birthday. Linda was unable to associate her symptoms with a clear precipitant to the MDD but was able to accept that her increasing age (and associated losses) did have an impact on her mood. The IPT-B model did not have an impact on Linda's presenting problems and indeed, the brief time-limited nature of the intervention was perhaps one of the problems, as highlighted by her belief that her problems were *"...too longstanding."* Due to the chronic nature of Linda's difficulties and the severity of depression at follow-up, she agreed to continue with further psychological intervention after the final follow-up. Linda continues to in treatment in the Department of Clinical Psychology.

2.3 AIM 1: TO DETERMINE WHETHER IPT-B IS EFFECTIVE IN REDUCING THE SYMPTOMS OF DEPRESSION IN IAN and LINDA

2.31 Revised Hamilton Rating Scale for Depression: Clinician Version (Warren, 1994)

Table 18.0 gives the means and standard deviations of the RHRSD Total Score for the verification group (Warren, 1994) and normative data for non-depressed adults. Table 19.0 gives the Total Raw Score for pre-treatment and post-treatment (0, 2 and 4 months) obtained with Ian and Linda. The scores were used to determine an initial diagnosis and to compare pre and post-treatment using criteria as suggested by Jacobson and Truax (1991)[1].

[1] Jacobson & Truax (1991) suggest criteria for the evaluation of **clinically significant** changes in psychotherapy. The authors suggest that if normative data aer available for a non-dysfunctional population and/or a dysfunctional

Source	Format	Group	Initial		Follow-up	
			M	*SD*	*M*	*SD*
RHRSD verification sample (Warren,1994)	Observer	Depressed Adults (171)	17.2	7.3	8.3	5.2
	Self-report (paper)	Depressed Adults (168)	17.9	8.8	10.8	7.9
Fava, KelLindaer, Munari, & Pavan (1982)	Observer	Non-depressed Adults	6.1	5.1	-	-
Robbins, Alessi, & Colfer (1985)	Self-report (paper)	Non-depressed Adults	16.0	8.7	-	-

Table 18.0: Means and Standard Deviations for various Versions of the Hamilton Reported.

Source	Format	Sample Case	Baseline Total raw score	Follow-up Discharge (0 months)	Follow-up (2 months)	Follow-up (4 months)
RHRSD	Observer	IAN	19	3	0	2
	Self-report (paper)	IAN	31	22	6	6
RHRSD	Observer	LINDA	25	21	23	22
	Self-report (paper)	LINDA	28	26	27	26

Table 19.0: Raw Scores obtained with IAN and LINDA for the Revised Hamilton Rating Scale for Depression.[2]

Patients are typically characterised as experiencing Minor Depression with a Total RHRSD Score of 11-16; Major Depression with a score of 17-25 and Severe Depression with a score of greater than or equal to 26. The initial assessments provided an 'observer rated' RHRSD Total Score of 19 for Ian and 25 for Linda, both of which fell within the range of major depression (17-25). Warren (1994) suggests that on the RHRSD, a post-treatment score of 10 or less or a decrease by 1/3 in initial severity is considered to represent successful treatment response over the short term (0-6 months).

For Ian, the Total Raw Score decreased by 16 (greater than 1/3 in initial severity and below the cut-off score of 10) immediately post treatment. At 2 and 4 months follow-up the Total Raw Score decreased by 19 and 17 respectively (from baseline data). Using The Jacobson and Truax (1991) criteria for clinically significant changes in psychotherapy, the level of functioning after treatment placed Ian closer to the mean of the functional group (non-depressed adults) than the mean of depressed adults *after treatment* on both forms of the

group for the standardisation measures, there are three criteria by which clinical significance may be operationalised:

- The level of functioning **after** treatment should fall outside the range of the dysfunctional population (+2 S.D in the direction of the normal referenced group).
- The level of functioning should fall within the range of the non-dysfunctional group.
- The level of functioning should place the client closer to the mean of the functional group than the mean of the dysfunctional group.

[2] The conventional way of reporting Hamilton Ratings is in terms of raw scores.

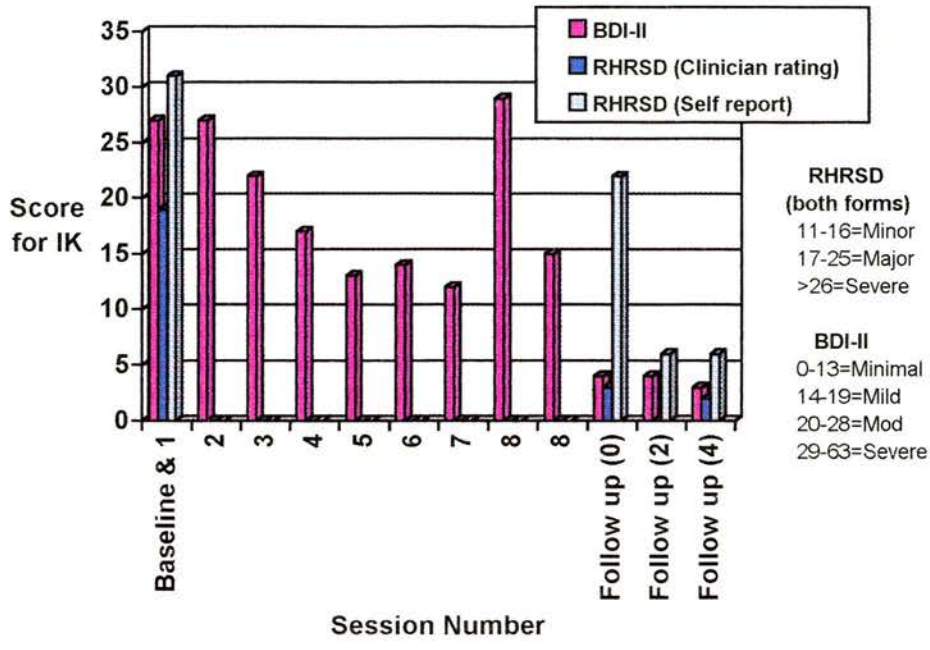
RHRSD (Table19.0). Indeed, examining the clinical significance of change with reference to the present study population, Ian's scores on both versions of the RHRSD were **clinically significant**, according to Jacobson and Truax, (1991, Table 20.0).

As a *statistical* measure of whether Ian improved over the course of treatment, Jacobson's Reliable Change Index: RCI was employed (Jacobson and Truax, 1991). The RCI determines whether the observed change is greater than the change which would be expected on the basis of the error in the measure. The results demonstrated that at all 3 follow-up times, the RCI exceeded 1.96 and therefore we can be reasonably confident that the improved status was not just due to the inherent unreliability of the test (RCI at end of treatment=3.87; at 2-month follow-up=4.6 and at 4-month follow-up=4.12, Appendix 13.0). Graph 11.0 depicts Ian's baseline and follow-up data for clinician and self-rated versions of the RHRSD. With Linda, the RCI was carried out as a statistical measure to **confirm** no significant change for the major outcome measure of the RHRSD (Appendix 13.0).

2.32 Revised Hamilton Rating Scale for Depression: Self-Report Inventory (Warren, 1994)
Ian initially scored 31, indicating a more severe depression, particularly when compared with the norms in Table 18.0. Ratings for both baseline assessment and follow-up were low for inconsistency suggesting that Ian rated himself consistently throughout (see Graph 11.0).

The Reliable Change Indices were calculated as being RCI at end of treatment=1.91; at 2-month follow-up=5.32 and at 4-month follow-up=5.32. 2 and 4-month follow-up data indicate that the improved status was not just due to the possible unreliability of the test (Appendix 13.0). For Linda, the RCI confirmed no significant change for the Self-Report version of the RHRSD.

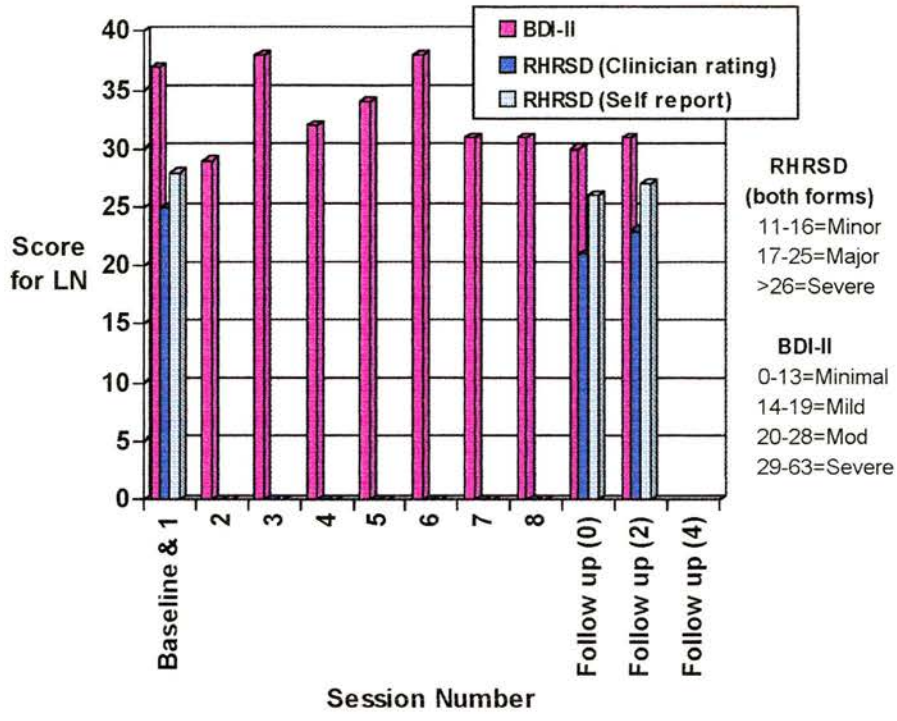
2.33 Beck Depression Inventory - II (Beck, 1996)
At baseline assessment, Ian rated with moderate depression on the BDI-II = 27 (Beck, 1996) and throughout treatment, scores decreased in severity (see Graph 11.0). Results reflected minimal depression according to the BDI-II post-treatment at 0 and 4 months.



Graph 11.0 BDI-II Scores and Pre & Post Treatment RHRSD (clinician rated) and RHRSD (self report) Scores for IAN

The Reliable Change Index was calculated as being RCI=2.75 at the end of treatment; RCI=5.28 at 2 months follow-up and RCI=5.50 at 4 months follow-up (Appendix 13.0) all of which exceed 1.96 and therefore, with reasonable confidence, it can be stated that the improved status was not just due to the possible unreliability of the test.

At baseline assessment, Linda rated with severe depression on the BDI-II = 37 (Beck, 1996) and throughout treatment, scores remained fairly stable in terms of severity (see Graph 12.0). By session 8, results reflected severe depression according to the BDI-II. RCI for Linda at end of treatment and at 2 and 4-month follow up all confirm no improved status.



Graph 12.0 BDI-II Scores and Pre & Post Treatment RHRSD (clinician rated) and RHRSD (self report) Scores for LINDA

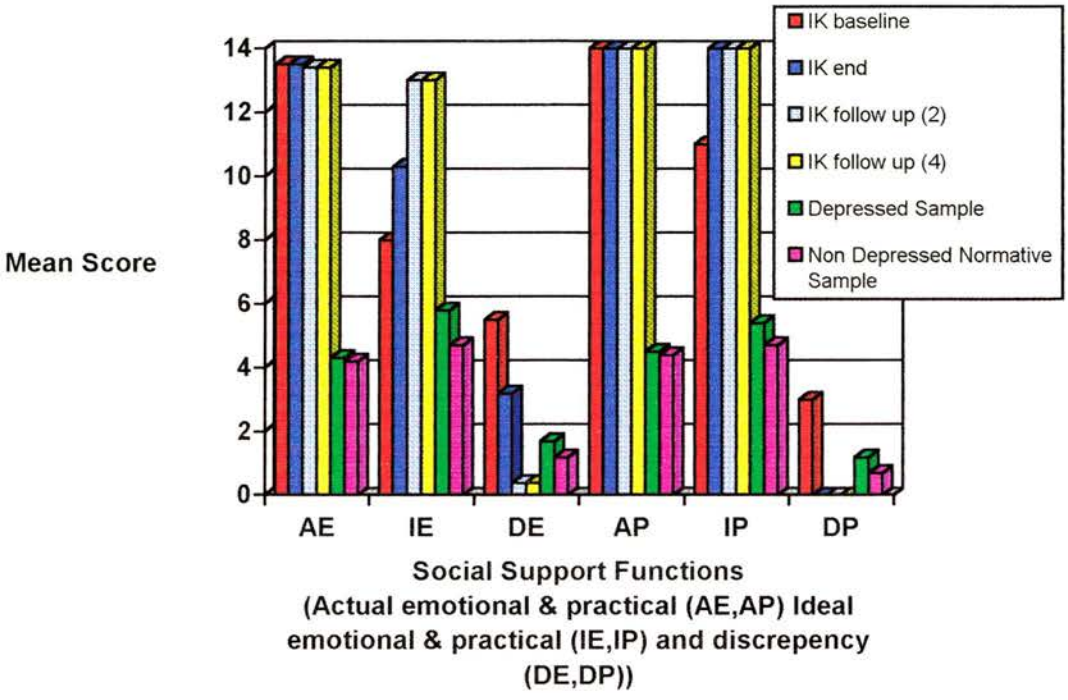
2.34 Summary of Clinically Significant Changes (according to Jacobson and Truax, 1991)
On all three major measures of outcome, RHRSD (both versions) and BDI-II, Ian demonstrated **clinically significant** improvement when compared to normative data and when compared to the present study population (Table 20.0). Linda did not demonstrate any such improvement when compared to either study population or normative data.

	RHRSD (CV)**≤11	RHRSD (PI)**≤19	BDI-II**≤15
Mean of pretest experimental group (M1)	17.67	22.59	29.59
Standard Deviation of pretest experimental group (S1)	6.53	7.42	11.64
Mean of well functioning normal population (Mo)	6.1	16	7.65
Standard Deviation of normal population (So)	5.1	8.7	5.9
Mean - IAN *(4 months FU)*	2**	6**	3**
Mean - LINDA *(4 months FU)*	22	26	31

Table 20.0: Demonstration of Clinical Significance According to Jacobson and Truax (1991) Criteria for the Evaluation of Changes in Psychotherapy.

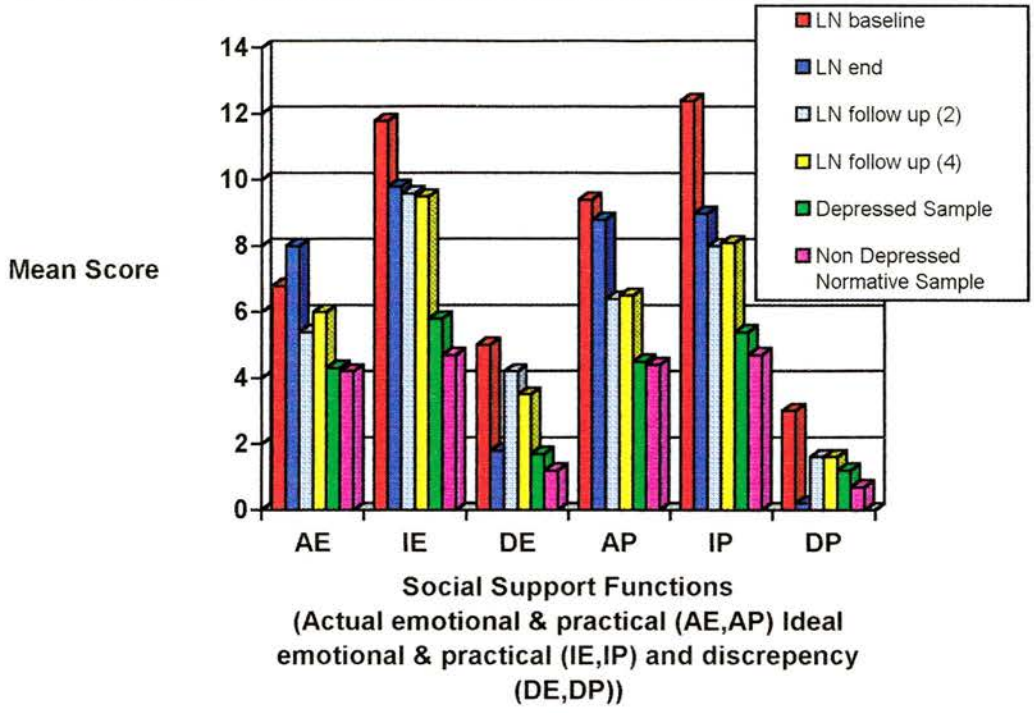
2.4 AIM 2: TO DETERMINE WHETHER IPT-B IS EFFECTIVE IN IMPROVING THE QUALITY OF INTERPERSONAL RELATIONSHIPS

2.41 Significant Others Scale (Power, Champion and Aris, 1988) for IAN and LINDA
Results indicated that at baseline, Ian initially reported a fairly high discrepancy between the **actual** and **ideal** levels of both emotional and practical support, especially when compared to those for depressed and non-depressed normative samples (Graph 13.0). Over time, the discrepancy reported between actual and ideal levels of emotional and practical support had decreased to *less* than that reported by non depressed normative samples.



Graph 13.0 Mean SOS Scores with IAN and Normative Samples

In terms of Significant Others for Linda, she reported an initial decrease in the discrepancy between the ideal and actual emotional support, however by 2-month follow-up this discrepancy had widened and did not return to the level initially reported (Graph 14.0). For practical support, the discrepancy changed from baseline to end of treatment (3.0 to 0.2) and by 2-month follow-up had increased to 1.6 and remained stable at 4 month follow-up. At baseline, Linda's overall ideal levels for both emotional and practical support were higher than either the depressed group or the non-depressed group supporting the suggestion that depressed patients typically have high or unrealistic expectations of themselves and of other people (Power and Champion, 1988).



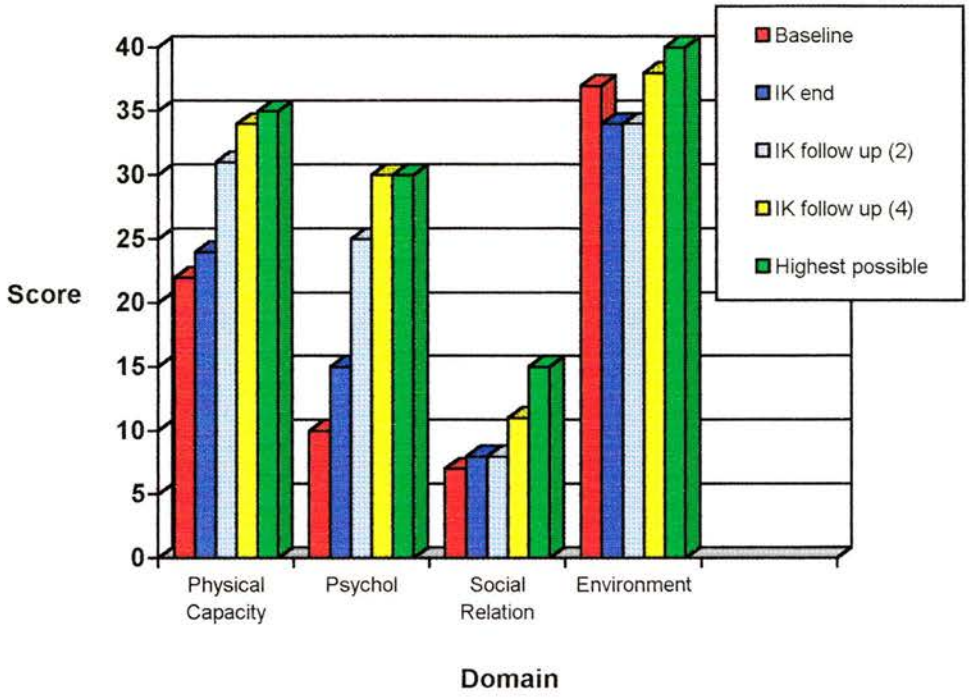
Graph 14.0 Mean SOS with LINDA and Normative Samples

2.42 World Health Organisation Quality of Life Scale (WHOQOL-BREF)

Four domain scores were derived, denoting Ian's perception of quality of life in each particular domain. Results demonstrated that the lowest scores at baseline assessment (using percentage of the highest possible score) were *'Psychological'* and *'Social Relationships'* (indicating lowest quality, as scores are scaled in a positive direction). Scores from baseline were compared with scores at follow-up to demonstrate any improvement in perception of quality of life within each of the four domains. By follow-up assessment 3 (4 months post end of treatment), Ian scored 100% of the highest possible score for the *'Psychological Domain'*.

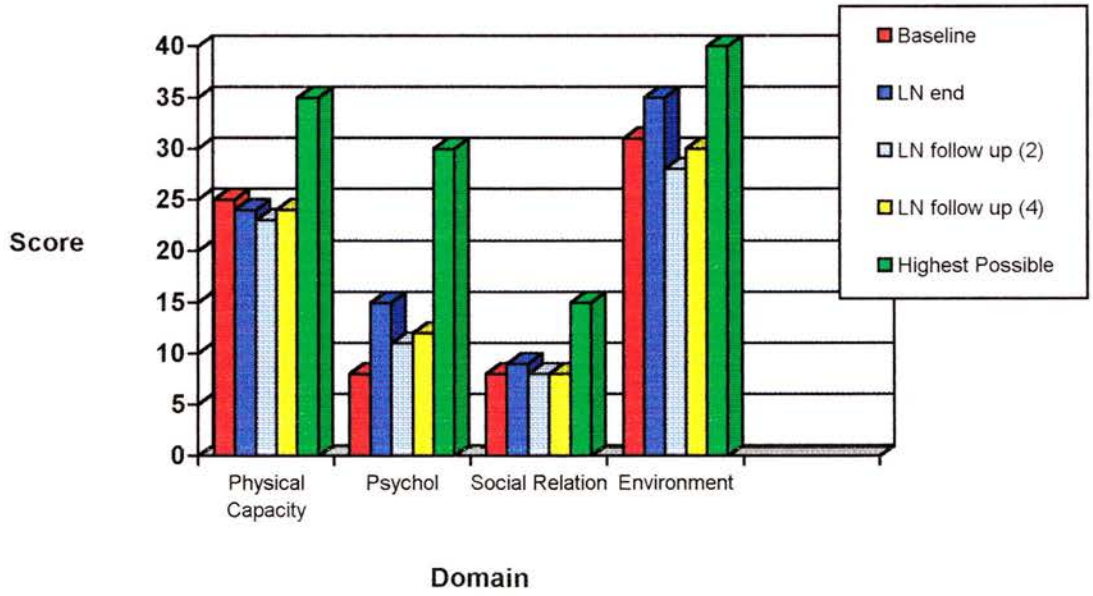
Domain	Highest Possible Score	IAN's Raw Score				IAN's Score expressed as a percentage of highest possible score			
		B/L	FU1	FU2	FU3	B/L	FU1	FU2	FU3
Physical Capacity	35	22	24	31	34	62.8	68.5	88.5	97.1
Psychological	30	10	15	25	30	33.3	50	83.3	100
Social relationships	15	7	8	8	11	46.7	53.3	53.3	73.3
Environmental	40	37	34	34	38	92.5	85	85	95

Table 21.0 WHOQOL Scores for IAN over Treatment



Graph 15.0 WHOQOL-Bref Version for IAN

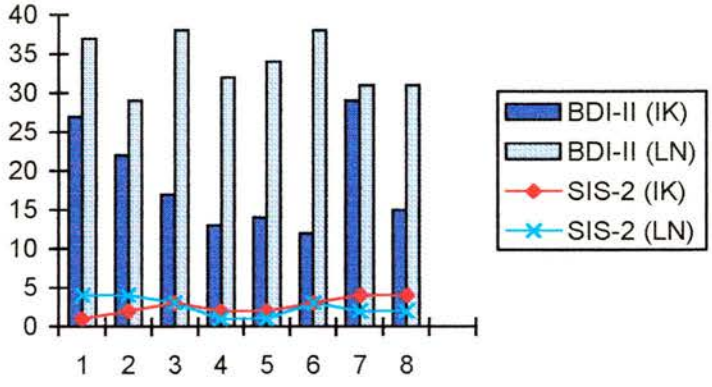
Results demonstrate that Ian's perception of quality of life improved over the course of treatment and at the end of treatment and continued to improve over 4 months follow-up. Results for Linda demonstrated little change over treatment and at follow-up (Graph 16.0).



Graph 16.0 WHOQOL-Bref Version for Linda

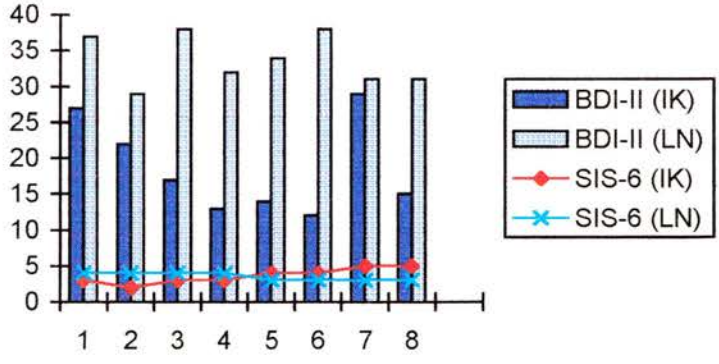
2.5 INDIVIDUAL TARGETS

Two of the most interesting results from the Session Impact Scale (Elliot and Wexler, 1994) were obtained with questions 2 and 6: *"I realised something new about someone else; I feel that my therapist understands me"* respectively. The scale scores from 1-5 with 1 = *not at all* and 5 = *very much.*



Graph 17.0: BDI-II Scores for Case Studies (IAN and LINDA) with Session Impact Scale Question 2: *"I realised something new about someone else "*

Results indicated that as treatment progressed over time, Ian reported that he was beginning to realise something new about someone else - a sense of "newness" had to be present. With this sense of newness, the reported severity of depression had decreased (BDI-II = 15) at session 8 (this questionnaire was not administered at the 2 and 4 month follow-up interviews, as it applied to the therapeutic interaction). Session 7 coincided with Christmas and Ian's financial fears that he would be unable to buy presents for his family, hence the elevated BDI-II score.



Graph 18.0 BDI-II with Session Impact Scale Question 6: *"I feel that my therapist understands me."*

Results indicated that as treatment progressed over time, the severity of depression for Ian decreased with a reported increase in feeling more understood by the therapist. Results from the contact and support suggested that Ian did not receive any kind of external support throughout the course of treatment. Linda showed very little variation with regards to feeling

understood by the therapist and therefore this particular factor could be interpreted as being less important to the recovery process for Linda.

2.6 DISCUSSION OF THE TWO SINGLE CASE STUDIES

Evaluation of the single-case data was carried out according to both clinical and experimental criteria whereby *clinical criteria* answers the question: Has the patient achieved an acceptable level of improvement? *Experimental criteria* concern the confidence which one may have in the belief that the intervention produced any observed effect.

For the 'successful treatment' case, the results obtained from the RHRSD at baseline assessment and follow-up, indicated a marked decrease in the severity of depression over time (immediately following treatment, 2 and 4 months post treatment). According to both Jacobson and Trux's (1991) and Warren's (1994) criteria for judging success, Ian did achieve an acceptable level of improvement and certainly made a **clinically significant** change over time. Results demonstrated that Ian's scores fell within the range of the non-dysfunctional group (using both normative data and the study population data as the dysfunctional group) and indeed were lower than the cut-off as sited by Warren (1994), as being an indicator of success at 2 and 4 months follow-up. There were no reported changes for Linda in the RHRSD and therefore she cannot be said to have achieved an acceptable level of improvement.

In terms of experimental criteria, Jacobson's Reliable Change Index applied to Ian's data allowed the judgement that in the Clinician Version of the RHRSD, the improved status was not just due to the possible unreliability of the test nor to regression to the mean at 4 month follow-up. Therefore, we can be confident that the change occurred in Ian as a result of therapy and not as a result of testing, reactivity, regression or maturation (as discussed earlier).

Ian reported that all depressive symptoms had decreased both in terms of quantity and severity. One of the primary aims of IPT-B was to reduce the symptoms of depression and given the results presented for Ian, this aim was certainly achieved on both clinical and experimental criteria at 4 months follow-up. Given the results presented for Linda, this aim was clearly not achieved on either clinical or experimental grounds.

Perhaps one of the most interesting results for Ian, was the change in discrepancy score over time with regards to the discrepancy between *ideal* and *actual* emotional and practical social support. Over time, the discrepancy reported decreased to ***less*** than that reported by non depressed normative samples. The model of therapy (IPT-B) focused on expectations of self and others, particularly during the session whereby an interpersonal inventory was completed. Perhaps this session in particular was most meaningful in helping Ian to challenge some of his expectations. When the comparison is made between what might be considered successful versus unsuccessful treatment, it is clear from the results that Linda was unable to sustain the changes that she had made over the course of therapy. Also, despite Linda's discrepancy score for emotional and practical social support changing over the course of time, this did not appear to have any impact on her mood, as reflected objectively through the BDI-II score.

A more in-depth examination of the initial **ideal** reported levels of emotional and practical support reveals a potential difference between what may have contributed towards the success or not (in terms of outcome) for the present study. Ian initially reported that his ideal levels of both practical and emotional support were ***less*** than he was actually receiving at baseline (i.e. Ian actually wanted to receive less support than he was getting) whereas Linda perceived herself as not receiving ***enough*** support, either practically or emotionally. This

may be a reflection of Ian's initial belief that it was not such a good idea to ask others for help. Perhaps one of the most therapeutic components of IPT-B for Ian was his acknowledgement that he did need help from other people and that it was beneficial to ask for it (in terms of having a positive impact on his mood). As time progressed, Ian responded that his ideal emotional and practical support was increasing, i.e. it was becoming more acceptable for him to need and therefore ask for others' help, thus having an impact on his mood as reflected through the BDI-II and RHRSD. Although Linda made changes in her social world which contributed towards her perception of the discrepancy between *ideal* and *actual* levels of both emotional and practical support reducing over time, she was unable to sustain these changes which perhaps was reflected in her mood (BDI-II and RHRSD).

Ian reported a marked increase in all four domains of quality of life which indicated that as therapy progressed, he perceived an improved quality of life. Linda however reported a decrease in her perceived quality of life and in the Physical Capacity Domain, this actually decreased for every assessment. As an interesting point, Linda noted no change in the quality of her social relationships over the course of therapy and over 4-month follow-up, perhaps again reflected in her low mood and subsequent severity of depression.

Treatment specific measures were also completed post-treatment by the therapist in order to assess adherence to the IPT-B model. Throughout treatment for both Ian and Linda, it was determined that the therapist did adhere to the IPT-B model. Tapes were rated by a trained supervisor in IPT to provide an objective independent rating of adherence to IPT-B; ratings reflected that the therapist was indeed adhering to the model.

External contact was also assessed in order to minimise effects from any external source. Throughout treatment Ian did not contact any external agency and therefore any external bias which may have produced an effect during therapy can be excluded. Linda did however contact external agencies and as such external bias may have been introduced to her ratings. Linda contacted the following over the course of therapy:

1. aromatherapist
2. dietician (for advice with regards to symptoms of Irritable Bowel Syndrome)
3. yoga
4. acupuncture

DIFFERENCES	IAN	LINDA
Initial severity of depressive symptoms	'Moderate' according to BDI-II (27)	'Severe' according to BDI-II (37)
Sex	Male	Female
Marital Status	Recently separated from 2nd wife	Married
Chronicity of problems	Clear and recent onset of depressive symptoms	Chronic (more than 10 years) nature of symptoms
Ideals with regard to emotional and practical support from others.	Ian initially did not expect or desire help from others but slowly began to use his social support network appropriately.	Linda initially perceived that others did not give as much social support as she needed. Initial ideal levels of social support were high perhaps reflecting unrealistic expectations of others.
External Bias	No reported external agencies involved in care of Ian over the course of IPT-B	Different external agencies involved as described above

Table 22.0: Summary of Major Differences between 'Successful' and 'Unsuccessful' Treatment

SIMILARITIES	IAN	LINDA
Age	53	51
Employment status	Full time	Full time
Children	2 adult children in regular contact	2 adult children in regular contact

Table 23.0: Summary of Major Similarities between 'Successful' and 'Unsuccessful' Treatment

From the similarities and differences between the two case studies presented (Tables 20.0 and 21.0) as illustrative examples of 'successful' IPT-B and 'unsuccessful' IPT-B, it would appear that the *differences* between Ian and Linda have contributed to a greater extent to the outcome than the *similarities.* The results of these two case studies should also be viewed in relation to the larger picture of the full study and in terms of **clinical significance** using the primary outcome measures of RHRSD (both clinician-rated and self-report versions). For the clinician-rated version, 66% of the IPT-B Treatment Group reached Jacobson and Truax's (1991) criteria for clinically significant change by 2-month follow up whilst 73% reached the same criteria on the self report version of the RHRSD.

IPT ADAPTATIONS: MANUALS AVAILABLE

MANUAL	AUTHOR(S)	SOURCE
Maintenance IPT for Recurrent Major Depression	Frank, E., Kupfer, D.J., Cornes, C. & Morris, S,M.	In Klerman, G.L. and Weissman, M.M. (1993). *New Applications of Interpersonal Psychotherapy,* p75-102. Washington, D.C.: American Psychiatric Press.
IPT for Dysthymic Disorder (IPT-D)	Markowitz, J.C.	*Interpersonal Psychotherapy for Dysthymic Disorder* (Chapter 12). Washington, D.C.: American Psychiatric Press.
IPT for Depressed Adolescents (IPT-A)	Mufson, L., Moreau, D., Weissman, M.M and Klerman, G.L. (1993).	*Interpersonal Psychotherapy for Depressed Adolescents.* (Chapter 13). New York: Guilford Press
IPT for Late-Life Depression	Frank, E., Frank, N., Cornes, C., Imber, D., Miller, M.D., Morris, S.M. and Reynolds, C.F. III.	In Klerman, G.L. and Weissman, M.M. (1993). *New Applications of Interpersonal Psychotherapy,* p167-198. Washington, D.C.: American Psychiatric Press.
Conjoint IPT for Depressed Patients with Marital Disputes (IPT-CM)	Weissman, M.M. and Klerman, G.L.	In Klerman, G.L. and Weissman, M.M. (1993). *New Applications of Interpersonal Psychotherapy,* p103-128. Washington, D.C.: American Psychiatric Press.
IPT for Bipolar Disorder (Interpersonal Social Rhythms Therapy)	Frank, E.	**Unpublished:** contact Professor of Psychiatry, Western Psychiatric Institute and Clinic, 3811 O'Hara Street, Pittsburgh, PA 15213.
IPT for Primary Care and Medically Ill Patients	Schulberg, H.C., Scott, C.P., Madonia, M.J., and Imber, S.D.	In Klerman, G.L. and Weissman, M.M. (1993). *New Applications of Interpersonal Psychotherapy,* p265-291. Washington, D.C.: American Psychiatric Press.
Interpersonal Counselling (IPC)	Weissman, M.	**Unpublished:** contact: Weissman, M. Columbia University College of Physicians and Surgeons, 1051 Riverside Drive, Unit #24, New York, NY 10032
IPT for Depressed HIV-Positive Patients (IPT-HIV)	Markowitz, J.C., Klertman, G.L., Clougherty, K.F. and Jospephs, L.	**Unpublished:** contact Markowitz, J. 525 East 68th Street, New York, NY 10021.Manual for Interpersonal Therapy with HIV-Seropositive Subjects.
IPT for Depressed Antepartum Patients	Spinelli, M.	**Unpublished:** Contact Spinelli, M. Columbia University College of Physicians and Surgeons, 722 West 168th Street, New York, NY 10032

IPT for Substance Abuse	Rounsaville, B.J. & Carroll, K.	Interpersonal Psychotherapy for patients who abuse drugs. In Klerman, G.L. and Weissman, M.M. (1993). *New Applications of Interpersonal Psychotherapy,* p319-352. Washington, D.C.: American Psychiatric Press.
IPT for Bulimia Nervosa	Individual format: Fairburn, C., *Interpersonal Psychotherapy for Bulimia Nervosa.* Group format (IPT-G): Wilfley, D.E. *Interperosnal Psychotherapy Adapted for Group (IPT-G) and fro the Treatment of Binge Eating Disorder.*	Fairburn In Klerman, G.L. and Weissman, M.M. (1993). *New Applications of Interpersonal Psychotherapy,* p353-378.. Washington, D.C.: American Psychiatric Press. Wilfley - Yale Binge Eating Tratment Study, **unpublished** (1993).
IPT for Social Phobia	Lipsitz, J., Markowitz, J.C., and Cherry, S.	Manual for Interpersonal Psychotherapy for Social Phobia. Columbia University College of Physicians and Surgeons, **unpublished** (1997).
IPT for Borderline Personality Disorder	Angus, L and Gillies, L.A.	Counselling the borderline client: an interpersonal approach. *Canadian Journal of Counselling/Revue canadienne de counseling,* (1994) **28**:69-82.
IPT Patient Guide	Weissman, M.M.	*Mastering Depression: A Patient Guide to Interpersonal Psychotherapy.* San Antonio, Tex.,: The Psychological Corporation, Order Service Centre, P.O. Box 839954, San Antonio, Texas.

DEVELOPMENT OF IPT-B TREATMENT MANUAL
Taken from Weissman et al. (2000)

STEP *from Weissman et al., (2000)*	**DESCRIPTION OF RESPONSE** *from present author*
Clinical experience, with both IPT and with the treatment population in question, is a prerequisite to developing a manual. The researcher should be certified in IPT and familiar with the target illness and its treatment approaches.	The present author has been trained in IPT and was familiar with the target illness and its treatment approaches.
A needs assessment may be carried out of the population under study.	Within Primary Care (in Fife), patients treated for depression are seen for an average of 6-8 sessions, mainly using the Cognitive Behavioural Model for Depression (Beck *et al.*, 1979).
Modifications of IPT derived from the needs assessment can be addressed in the manual through the development of case vignettes and scripts.	IPT was adapted to IPT-B utilising advice from Wilfley *et al.*, (1998) on how to adapt a treatment and comparisons drawn with IPC (Interpersonal Counselling).
Once a manual has been developed, it deserves to be tested before being used in a treatment trial. Pilot cases may bring to light problems with the manual, or raise new issues that should be added to it.	IPT-B was used with a single case (DF) and is discussed at length in the Methods Chapter. Problems were raised and changed for the current trial.
The goal is to have a manual that is sufficiently comprehensive that it influences therapists.	Results from the pilot Case Study indicated IPT-B to be used within a larger N. The next stage in the process is to use IPT-B manual with other therapists currently having completed the didactic part of the IPT training.

DETAILED DESCRIPTION OF PRELIMINARY STAGE: THE SINGLE CASE STUDY

The single case-study design (characterised by repeated measures of a quantitative variable on a single case) was employed as it offered a method of investigating fluctuations in behaviour and symptoms over time - the effects of the treatment, IPT-B, were judged against these fluctuations. The design was a non-randomised, one-group experimental design, in which the individual participant (DF) served as her own control.

The design for the single case was based on the AB design whereby A and B represented a series of repeated observations under 2 conditions:

1. Baseline (A)
2. Treatment (B)

By taking repeated measurements, testing, reactivity, regression and maturation were assessed and controlled.[3] Each of these threats would be expected to produce a systematic trend in the sequence of baseline data points. The effectiveness of the treatment, IPT-B, was judged by the extent to which the data points shifted when the intervention was introduced, and by whether the change was sustained throughout the intervention.

DF was assessed at 0 and 6 months post-treatment, in order to determine whether any observed changes were sustained post intervention.

To some extent the AB design can provide a control for the effects of history. If the client's (DF) behaviour was reasonably stable during baseline and treatment phases, despite the documented presence of various extraneous events, it is not unreasonable to infer that any major change occurring at the time of introducing treatment is due to the treatment. In order to determine whether any other contact with external agencies could have influenced the results by producing a therapeutic effect, DF completed the 'Contact and Support' questionnaire on a weekly basis.

A combination of sufficient data points, careful documentation of treatment and extra-treatment events, and systematic and cautious analyses of variability and change justified the use of the AB design in the pilot study. A combination of the above features enabled the inference to be made that the treatment **caused** an effect (i.e. it increased the internal validity of the study). All of the points raised above (including Kazdin's (1981) characteristics that improve the credibility of the single case study[4]) were taken into account in the original design of the study.

The Procedure with the Single Case

A contract was discussed with DF with an agreement for 8 sessions and 2 review sessions. The first review session was scheduled for immediately post-treatment (0 months) and the second review was scheduled for 6 months post-treatment as time permitted. DF also gave her permission to be audiotaped for future research purposes and for rating adherence to the IPT-B model.

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[3] *Testing* is the general name given to effects, which can occur when subjects are measured repeatedly. Each measure is likely to show different specific effects of testing. People may learn to 'fake good' or 'bad' on symptoms checklists. Measurement may also be *reactive* so that the very act of measurement provokes a significant change in the subject's behaviour. Reactivity usually declines in time so that changes between 2 occasions may not be due to a 'true' change but merely to a decrease in reactivity. Reactivity is a significant feature but it can usually be removed by taking repeated measures, which are expected to stabilise after some time.

[4] Systematic, quantitative (versus anecdotal) data; multiple assessments of change over time; change in previously chronic or stable problems; immediate or marked effects following the intervention.

During treatment, individual targets were assessed using the following:
1. Beck Depression Inventory II (Beck, 1996).
2. Session Impact Scale (Elliot and Wexler, 1994) adapted format to assess 6 key areas of the impact of therapy.
3. Contact and Support Scale to assess any external contributors to differences in DF's presentation.

Immediately post session, the following questionnaires were completed by the therapist (Rounsaville *et al.,* 1986):
1. Checklist and Rating Form: either *initial sessions* or *termination.*
2. Therapist Strategy Form and Role Transitions Rating Form.
3. Process Rating Form.
4. Overall Therapy Rating Form.

IPT-B - The manual for the single case
The manual is structured as follows:
1. Outline of the structure of IPT-B in three phases: assessment, middle and termination.
2. Overview of the sessions.
3. Session by session account with possible agendas to follow (detailing specific strategies).

The pilot study manual was developed for the particular focus chosen with the single case (DF) and therefore incorporated a focus of 'Role Transition'.

DF: The Single Case
The initial criteria for inclusion in the study included a referral for depression with no other Axis I or II criteria mentioned in the referral letter. DF was the single case who reached a diagnosis of Major Depressive Episode, as rated by the Revised Hamilton Rating Scale for Depression (Warren, 1994), according to DSM-IV (APA, 1994) criteria.

DF was a 27-year-old, married woman with a 2-year-old daughter who presented with a clear onset of depressive symptoms.

Using the single case design, DF, who received IPT-B, showed overall considerable improvement.

INDIVIDUAL RESULTS FOR DF

Evaluation of the single-case data was carried out according to both clinical and experimental criteria whereby *clinical criteria* answers the question: Has the patient achieved an acceptable level of improvement? *Experimental criteria* concern the confidence which one may have in the belief that the intervention produced any observed effect.

Global Measures
Results obtained from both the clinical interview and the self-report problem inventory of the RHRSD at baseline assessment and follow up, indicated a marked decrease in the severity of depression over time (immediately following treatment and 6 months post treatment). According to both Jacobson and Trux's (1991) and Warren's (1994) criteria for judging success, DF did achieve an acceptable level of improvement. Results demonstrated that DF's scores fell within the range of the non-dysfunctional group and indeed were lower than the cut-off as sited by Warren (1994) as being an indicator of success.

In terms of experimental criteria, Jacobson's Reliable Change Index allowed the judgement that in the Clinician Version of the RHRSD, the improved status was not just due to the

possible unreliability of the test nor to regression to the mean. Therefore, we can be confident that the change occurred in DF as a result of therapy and not as a result of testing, reactivity, regression or maturation (as discussed earlier).

DF reported that all depressive symptoms had decreased both in terms of quantity and severity. One of the primary aims of IPT-B was to reduce the symptoms of depression. Given the results presented, this aim was certainly achieved on both clinical and experimental criteria for immediately post treatment. The results at 6 month follow up cannot be reported as being due to treatment given that at approximately 4 months post treatment, DF returned to her GP stating that she was *"feeling rather down"*. DF was prescribed antidepressants (Paroxetene) and therefore, all 6 month follow up data has to be interpreted with caution. It does, however, provide an important suggestion for further research with IPT-B. Within the present study there were no follow up 'floating sessions' which could be taken at the patient's discretion, due to time limitations. In further studies, it would be highly recommended that 2 floating sessions in the 6 months post treatment were built in to therapy to encourage use of the strategies of IPT-B in the first instance rather than an immediate transfer to prescribed medication.

SOS - B Version

Perhaps the most interesting result was the change in discrepancy score over time with regards to the discrepancy between *ideal* and *actual practical* support - DF rated initially that she was actually receiving too much practical support. The model of therapy (IPT-B) focused on expectations of self and others, particularly during the session whereby an interpersonal inventory was completed. Perhaps this session in particular was most meaningful in helping DF to challenge some of her expectations. When the results for Session Impact Scale are examined, it was after this particular session that DF rated the question *"Realised something new about myself"* highest.

WHO-QOL-Bref Version

In terms of quality of life, as perceived by DF, there was a marked increase in scores over all 4 domains, indicating that as therapy progressed, DF perceived that she had an improved quality of life across all domains.

Another particularly interesting finding was that at follow up, DF chose to rate 3 extra key people in her life, perhaps as a direct result of drawing out an Interpersonal Inventory and examining the opportunities available in DF's social network.

Individual Targets

In terms of improving the quality of data obtained, standardised measures of change were employed throughout therapy. The BDI-II was administered on a weekly basis and results clearly indicated a decrease in severity of reported depressive symptoms over time. Again, 6 month data has to be interpreted with caution due to effects of antidepressant medication.

Therapeutic Process

Results indicated that as DF's symptoms of depression decreased, perceptions of feeling understood by the therapist *and* realising something new about someone else, increased. Treatment specific measures were also completed post-treatment by the therapist in order to assess adherence to the IPT-B model. Throughout treatment, it was determined that the therapist did adhere to the IPT-B model. The limitation was that the therapist completed her own ratings and therefore could not control for bias. In the future, tapes would be passed onto a trained supervisor in IPT to rate the adherence of the therapist.

External contact was also assessed in order to minimise effects from any external source. Throughout treatment, DF did not contact any external agency and therefore any external

bias which may have produced an effect during therapy can be excluded. As stated earlier, 6 month data should be interpreted with caution due to an external bias of antidepressant medication taken approximately 4 months post treatment.

Generalisation of Findings

Perhaps the most important question to be asked of any study whereby a treatment has been adapted to a new format is: ***will this treatment be of use to other clients and clinicians?***

The most obvious limitation in studying a single-case is that it is not clear if the results from this case would be relevant to other cases. This concerns external validity or generalisation of findings from an experiment, so that it can be answered empirically. The present study considered 3 domains to which the findings of the case study may be generalisable:

1. *Population validity: to which members of which populations is this procedure useful or applicable?*

Initially, results would indicate that the model of IPT can indeed be adapted to a briefer format and used within Primary Care. Results also indicate that the model is effective (initially, in the short term) in reducing symptoms of depression and improving the quality of interpersonal relationships with patients presenting with mild-moderate depression.

2. *Ecological validity: how far can these findings be replicated with different experimenters, settings and measurement procedures?*

To date, all reported adaptations of IPT have used trained IPT therapists. In the early stages of the adaptation, the results of this study can only be applied to those trained in IPT. The therapy took place in Primary Care and therefore, the results cannot be said to be applicable to other settings as yet.

3. *Manipulation or construct validity (Cook & Campbell 1979): will a conceptually similar intervention have the same effect?*

A clinical replication series (Barlow & Hersen, 1984) may be conducted in the future to determine external validity of the therapy.

DIFFERENCES BETWEEN IPT, IPC AND IPT-B

IPT	IPC	IPT-B
Developed for clinical depression (3 component processes).	Developed for non-psychiatric patients who are in distress and have symptoms due to current stresses in their lives.	Developed for clinical depression.
Patient reaches full criteria for major depression.	Patient may have diagnosable psychiatric symptoms that **do not** meet established criteria for psychiatric disorders. The patient is viewed as a person in distress & experiencing symptoms & is not viewed as a patient with a specific psychiatric diagnosis.	Patient reaches full criteria for major depression.
Focused treatment for **depressive** symptoms.	Focused treatment for **stress** symptoms.	Focused treatment for **depressive** symptoms.
Goals of treatment: - to reduce symptoms of depression; - to improve social and IP functioning.	**Goals of treatment:** - to reduce stress; - to enhance social functioning through the encouragement of self reliance; - to reduce inappropriate[5] healthcare utilisation (based on the premise that use of a Healthcare system is a major mode of coping with stressors in the environment).	**Goals of treatment:** - to reduce symptoms of depression; - to improve social and IP functioning.
3 phases of treatment (detailed in the Comprehensive Guide to IPT (Weissman et al 2000) including case examples).	3 phases of treatment (detailed explicitly in a manual with precise written instructions).	3 phases of treatment (detailed in the IPT-B manual). Agendas feature as a guide.
16 sessions to be taken over 20 weeks.	6 sessions to be taken over 8 weeks.	8 sessions to be taken over 10 weeks.
Each session lasts 1 hour.	Each session lasts 30 minutes (first session lasts 1 hour).	Each session lasts 1 hour.
Is administered by trained professionals in IPT.	Can be administered by a non-mental health professional.	Is administered by trained professional in IPT.
Specific homework does not feature.	Homework features.	Homework features.
Primary measure of symptoms is BDI-II.	Primary measure of symptoms is GHQ.	Primary measure of symptoms is BDI-II.

[5] The IPC manual differentiates between inappropriate utilisation of the healthcare system (in the US) both from the perspective of the individual and society as a whole. It could be argued that despite our different forms of healthcare in the US and the UK, similar principles can be applied to the NHS in the UK.

SIMILARITIES BETWEEN IPT, IPC AND IPT-B

IPC and IPT-B are derived directly from interpersonal psychotherapy (IPT; Klerman et al. 1984).
The IPT manual was used as a general guide in developing both IPC and IPT-B.
IPT, IPC & IPT-B are not aimed at personality or character change.
IPT & IPT-B are not concerned with origin of depressive symptoms but uses their connection with IP problems as treatment focus. IPC is not concerned with the origins of the stress symptoms but again, uses their connection with IP problems with the "here and now" focus.
Treatment focuses on elucidating patterns in interpersonal relations and linking recent IP events to recent mood.
IPT, IPC & IPT-B are all conceptualised at 3 levels: strategies for specific tasks, techniques & therapeutic stance.
Therapist adopts a hopeful, supportive, non-neutral and active stance (i.e. patient advocate).[6]
Target of interventions in IPT, IPC & IPT-B is face-to-face interactions with significant others.
Specific techniques are the same across all 3 modes of therapy including: reassurance, clarification, improving communication (frequently by encouraging patients to tell others how they feel), testing perceptions and performance through IP contact (similar to CBT) and decision analysis.
Main task of the therapist is to ensure that the patient remains focused in the identified problem area(s), gains a better understanding of them and attempts to change the problem area(s).
Therapeutic relationship is not interpreted as transference.
Interpretation of dreams is not attempted.
Therapy does not attempt to uncover deeply unconscious conflicted areas.
Therapeutic relationship is not a friendship.

[6] "In adapting a treatment, it is important to identify the therapist and patient roles in the specified treatment and how changing the therapeutic [*time*] may alter them." (Wilfley et al 1998)

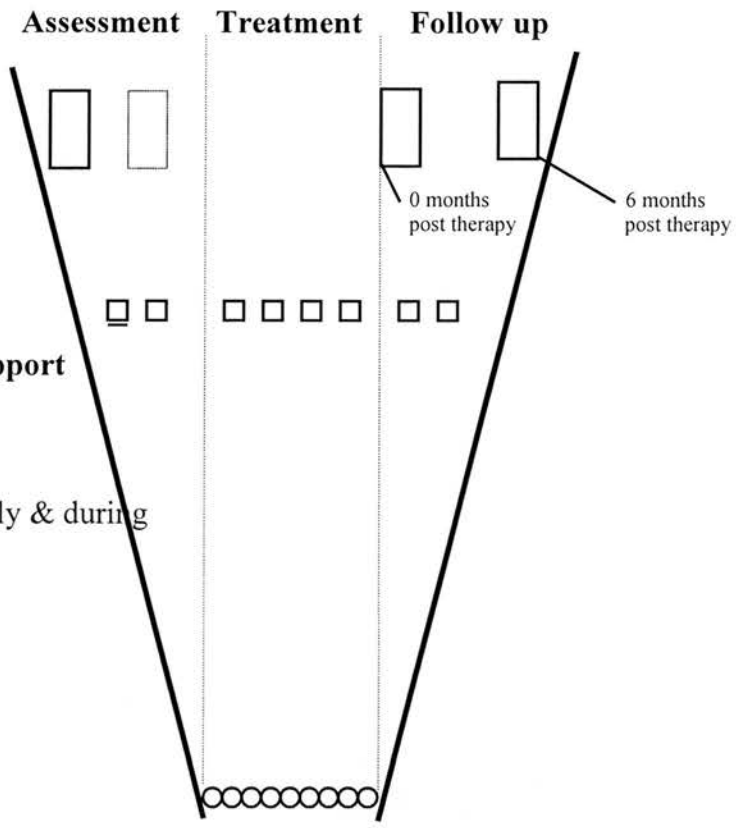
TREATMENT COMPARISONS BETWEEN IPT, IPC AND IPT-B

PHASE 1/ Assessment	IPT Sessions 1-4	IPC Sessions 1&2	IPT-B Sessions 1&2
	Diagnostic interview conducted & pertinent psychiatric history.	Review of symptoms	Diagnostic interview conducted & pertinent psychiatric history
	Discussion of diagnosis of depression.	Assessment of the chronology of the symptoms in relation to recent life events and stress	Discussion of diagnosis of depression.
	Sick role given with positive emphasis on *recovery.*	Determine who the key people are that the patient may be having difficulties with (similar to the Interpersonal Inventory but less detailed and less emphasis appears to be placed on the drawing out of such).	Sick role given with positive emphasis on *recovery.*
	Explanation of what treatment will entail.	Patient's distress reformulated into one of 4 problem areas: **1. unresolved grief** **2. role transitions** **3. role disputes** **4. loneliness & social isolation** Stated as not being mutually exclusive but 1 or 2 areas should be chosen.	Explanation of what treatment will entail.
	Interpersonal Inventory (patient's current close relationships & patterns of social functioning - also potential sources are identified.)		Interpersonal Inventory (patient's current close relationships & patterns of social functioning - also potential sources are identified.) *This will be written by the patient i.e an autobiographical statement.*
	Any changes in IP relationships close to the onset of depression are highlighted - to inform for future focus & to establish a context in which the depressive symptoms will be understood.		Any changes in IP relationships close to the onset of depression are highlighted - to inform for future focus & to establish a context in which the depressive symptoms will be understood.
	Therapist links the patient's depression to his or her IP relationships in the here and now.		Therapist links the patient's depression to his or her IP relationships in the here and now.

PHASE 2 - Middle	**IPT Sessions 5-12**	**IPC Sessions 3&4**	**IPT-B Sessions 3-6**
	Application of techniques as described by Klerman et al., 1984. Focus on one of four IP problem areas: 1. **grief following death of a loved one (abnormal grief reaction).** 2. **Role disputes (conflict with significant persons)** 3. **Role transitions (changed life situations)** 4. **Interpersonal deficits (sig. Social skills problems)**	Encouragement of patient's capacity for coping with the problem area (as defined above)	Application of techniques as described by Klerman et al., 1984. Focus on one of four IP problem areas: 1. **grief following death of a loved one (abnormal grief reaction).** 2. **Role disputes (conflict with significant persons)** 3. **Role transitions (changed life situations)** 4. **Interpersonal deficits (sig. Social skills problems)**
PHASE 3 Termination	**IPT Sessions 13-16**	**IPC Sessions 5&6**	**IPT-B Sessions 7&8**
	Recognition and consolidation of treatment gains Discussion of preventative measures for the future ***Patient is urged to continue until treatment is complete at 16 sessions.***	Encouragement of use of improved modes of coping with these problems Facilitation of independence Termination - 2 weeks after session 5. ***If the patient is sufficiently improved following any session, they are urged not to continue with therapy.***	Recognition and consolidation of treatment gains Discussion of preventative measures for the future ***Patient is urged to continue until treatment is complete at 8 sessions.***

IPC is described in a manual which gives direct and explicit instructions for what the health care professional should say in any given different scenario. IPT-B does not give such explicit instructions but offers agendas to be followed. Specific instructions are given only at the feedback of the formulation session whereby the focus is agreed upon between patient and therapist; these are guidelines and not strict instructions.

ASSESSMENT-EVALUATION FUNNEL
Morley, 1989



[7] Although self report measures of symptom intensity may be subject to instrumentation effects, in the present study an attempt was made to ensure that the scales had equally spaced intervals.

SESSION IMPACT SCALE
Elliot and Wexler, 1994

1. Realised something new about myself
As a result of the session, I now have a new insight about myself or have understood something new about me; I see a new connection or see why I did or felt something. (Note: there must be a sense of "newness" as a result of something which happened during the session).

1	2	3	4	5
Not at all	Slightly	Somewhat	Pretty Much	Very Much

2. Realised something new about someone else
As a result of the session, I now have a new insight about another person or have understood something new about someone else or people in general. (A sense of "newness" should be present).

1	2	3	4	5
Not at all	Slightly	Somewhat	Pretty Much	Very Much

3. More bothered by unpleasant thoughts and/or feelings, or more likely to push them away.
The session has made me think of uncomfortable or painful ideas, memories, or feelings that weren't helpful; it made me push certain thoughts of feelings away or avoid them.

1	2	3	4	5
Not at all	Slightly	Somewhat	Pretty Much	Very Much

4. Feel attacked or that my therapist doesn't care
As a result of the session, I now feel criticised, judged or put down by my therapist; I feel she is cold, bored or doesn't care about me.

1	2	3	4	5
Not at all	Slightly	Somewhat	Pretty Much	Very Much

5. Impatient or doubting of therapy.
As a result of the session, I now feel more bored or impatient with the progress of therapy or with having to go over the same old things over and over again; I have started to feel more that my therapy is pointless or not going anywhere.

1	2	3	4	5
Not at all	Slightly	Somewhat	Pretty Much	Very Much

6. Feel my therapist understands me
As a result of the session, I now feel more deeply understood, that someone else (my therapist) really understands what is going on with me or what I'm like as a person.

1	2	3	4	5
Not at all	Slightly	Somewhat	Pretty Much	Very Much

Diary for use in IPT Study

An Adaptation of Interpersonal Psychotherapy for Depression within Primary Care

Please record details of all contact with your GP and details of the kind of support you have received:

1. I have been to see my GP (record number of times):

Week 1	Week 2	Week 3	Week 4	Week 5	Week 6
.....times	.....times	.....times	.....times	.....times	.....times
How long was your contact with GP?	How long was your contact with GP?	How long was your contact with GP?	How long was your contact with GP?	How long was your contact with GP?	How long was your contact with GP? .....
Was this for depression? **Yes/No**	Was this for depression? **Yes/No**	Was this for depression? **Yes/No**	Was this for depression? **Yes/No**	Was this for depression? **Yes/No**	Was this for depression? **Yes/No**

Week 7	Week 8	Week 9	Week 10	Week 11	Week 12
.....times	.....times	.....times	.....times	.....times	.....times
How long was your contact with GP?	How long was your contact with GP?	How long was your contact with GP?	How long was your contact with GP?	How long was your contact with GP?	How long was your contact with GP? .....
Was this for depression? **Yes/No**	Was this for depression? **Yes/No**	Was this for depression? **Yes/No**	Was this for depression? **Yes/No**	Was this for depression? **Yes/No**	Was this for depression? **Yes/No**

2. What medications are you taking (just write *"same"* if it doesn't change over the weeks)

Week 1	Week 2	Week 3	Week 4	Week 5	Week 6
Name of medication:	Name of medication:	Name of medication:	Name of medication:	Name of medication:	Name of medication: .....
Dose of medication:	Dose of medication:	Dose of medication:	Dose of medication:	Dose of medication:	Dose of medication: .....

Week 7	Week 8	Week 9	Week 10	Week 11	Week 12
Name of medication: ..... Dose of medication:	Name of medication: ..... Dose of medication:	Name of medication: ..... Dose of medication:	Name of medication: ..... Dose of medication:	Name of medication: ..... Dose of medication:	Name of medication: ..... Dose of medication: .....

3. Have you met with any other health care professional (e.g. dietician, Physiotherapist) Record date and who you saw:

Week 1	Week 2	Week 3	Week 4	Week 5	Week 6
Date:	Date:	Date:	Date:	Date:	Date:
Who I saw:	Who I saw:	Who I saw:	Who I saw:	Who I saw:	Who I saw:

Week 7	Week 8	Week 9	Week 10	Week 11	Week 12
Date:	Date:	Date:	Date:	Date:	Date:
Who I saw:	Who I saw:	Who I saw:	Who I saw:	Who I saw:	Who I saw:

4. Have you had any contact with or received any treatment from anyone else (e.g. Aromatherapist, Reflexologist)

Week 1	Week 2	Week 3	Week 4	Week 5	Week 6
Date:	Date:	Date:	Date:	Date:	Date:
Who I saw:	Who I saw:	Who I saw:	Who I saw:	Who I saw:	Who I saw:

Week 7	Week 8	Week 9	Week 10	Week 11	Week 12
Date:	Date:	Date:	Date:	Date:	Date:
Who I saw:	Who I saw:	Who I saw:	Who I saw:	Who I saw:	Who I saw:

5. Have you made any lifestyle changes (diet, exercise, moved house, changed job?)

INITIAL SESSION(S) CHECKLIST AND RATING FORM
Rounsaville *et al.* (1986)

TASKS	**Yes**	**No**	**Rec**		**QUALITY** **Excellent**						**Poor**
Inquire re: chief complaint & depressive symptoms	1	2	3		1	2	3	4	5	6	7
History of current depressive episode	1	2	3		1	2	3	4	5	6	7
Brief Social History	1	2	3		1	2	3	4	5	6	7
Inquire re: patient's expectations re psychotherapy	1	2	3		1	2	3	4	5	6	7
Explanation of IPT/Basic assumptions	1	2	3		1	2	3	4	5	6	7
Translation of chief complaint (depressive symptoms) into interpersonal context	1	2	3		1	2	3	4	5	6	7
Reassurance re: positive prognosis	1	2	3		1	2	3	4	5	6	7
Explanation of IPT techniques	1	2	3		1	2	3	4	5	6	7
Contract setting (admin. details, length, frequency and duration of sessions & treatment, appointment times)	1	2	3		1	2	3	4	5	6	7
Interpersonal inventory	1	2	3		1	2	3	4	5	6	7
Feedback IPT formulation/Identify focus	1	2	3		1	2	3	4	5	6	7
Contract setting re: treatment goals	1	2	3		1	2	3	4	5	6	7
Exploration of therapist & patient tasks working towards treatment goals	1	2	3		1	2	3	4	5	6	7

Therapist Behvaiour	**Quality** **Excellent**						**Poor**
Appropriate activity level	1	2	3	4	5	6	7
Appropriate degree of supportiveness	1	2	3	4	5	6	7
Focus on current interpersonal functioning	1	2	3	4	5	6	7

TERMINATION SESSION(S) CHECKLIST AND RATING FORM

Rounsaville *et al.* (1986)

TASKS				QUALITY							
	Yes	No	Rec		Excellent						Poor
Explicit discussion of the end of treatment	1	2	3		1	2	3	4	5	6	7
Elicit/discuss patient's reaction to termination	1	2	3		1	2	3	4	5	6	7
Acknowledgement of the end of treatment as a time of potential grieving	1	2	3		1	2	3	4	5	6	7
Help patient move toward a recognition of his/her independent competence	1	2	3		1	2	3	4	5	6	7
Review the course of treatment & progress with the patient	1	2	3		1	2	3	4	5	6	7
Patient given the opportunity to evaluate the treatment & assess future needs	1	2	3		1	2	3	4	5	6	7
Assess with patient early warning signals, & discuss procedures for re-entry into treatment if necessary	1	2	3		1	2	3	4	5	6	7

FOCUS RATING FORMS
Rounsaville *et al.* (1986)

TRANSITION FOCUS

Goal Directed Activity	yes	no	rec		Excellent						Poor
Review depressive symptoms	1	2	3		1	2	3	4	5	6	7
Relate depressive symptoms to difficulty in coping with some recent life change	1	2	3		1	2	3	4	5	6	7
Review positive and negative aspects of old role and possible new ones	1	2	3		1	2	3	4	5	6	7
Explore feelings about what is lost	1	2	3		1	2	3	4	5	6	7
Explore feelings about the change itself	1	2	3		1	2	3	4	5	6	7
Explore opportunities in the new role.	1	2	3		1	2	3	4	5	6	7
Realistic evaluation of what is lost	1	2	3		1	2	3	4	5	6	7
Encourage appropriate release of affect	1	2	3		1	2	3	4	5	6	7
Encourage development of social support system and new skills called for in new role	1	2	3		1	2	3	4	5	6	7

GRIEF FOCUS

Goal Directed Activity	yes	no	rec		Excellent						Poor
Review depressive symptoms	1	2	3		1	2	3	4	5	6	7
Relate depressive symptoms to death of significant other	1	2	3		1	2	3	4	5	6	7
Reconstruct the patient's relationship with the deceased	1	2	3		1	2	3	4	5	6	7
Describe the sequence and consequences of events just prior to, during, and after the death.	1	2	3		1	2	3	4	5	6	7
Explore associated feelings (negative as well as positive)	1	2	3		1	2	3	4	5	6	7
Consider possible ways of becoming involved with others.	1	2	3		1	2	3	4	5	6	7

DISPUTE FOCUS

Goal Directed Activity	yes	no	rec		Excellent						Poor
Review depressive symptoms	1	2	3		1	2	3	4	5	6	7
Relate depressive symptoms' onset to overt or covert dispute with significant other and with whom patient is currently involved.	1	2	3		1	2	3	4	5	6	7
Determine stage of dispute: a. Renegotiation b. Impasse c. Dissolution	1	2	3		1	2	3	4	5	6	7
Understand how nonreciprocal role expectations relate to dispute	1	2	3		1	2	3	4	5	6	7
Are there parallels in other relationships?	1	2	3		1	2	3	4	5	6	7
How is the dispute perpetuated?	1	2	3		1	2	3	4	5	6	7

PROCESS RATING FORM
Rounsaville *et al.* (1986)

PROCESS	yes	no	rec	QUALITY Excellent						Poor
Exploratory techniques, supportive acknowledgement, extension of topic, non-directive exploration	1	2	3	1	2	3	4	5	6	7
Administartive details	1	2	3	1	2	3	4	5	6	7
Encourage expression of affect; inquiry into sensitive areas; acceptance/acknowldement of affect; inquiry into feeling associated with content	1	2	3	1	2	3	4	5	6	7
Clarification/confrontation; restructuring, rephrasing, feedback, development of interpersonal awareness, interpretation	1	2	3	1	2	3	4	5	6	7
Communication analysis	1	2	3	1	2	3	4	5	6	7
Use of the therapeutic relationship	1	2	3	1	2	3	4	5	6	7
Directive techniques, advice giving, limit setting, education, modelling, direct help	1	2	3	1	2	3	4	5	6	7
Decision analysis	1	2	3	1	2	3	4	5	6	7
Use of significant other	1	2	3	1	2	3	4	5	6	7
Other	1	2	3	1	2	3	4	5	6	7
Non IPT techniques e.g. behaviouristic, overly psychoanalytic	1	2	3	1	2	3	4	5	6	7

Problems with doing therapy	Client		Therapist	
	Yes	No	Yes	No
Lateness	1	2	1	2
Missed appointments	1	2	1	2
Changed topic/tangential	1	2	1	2
Direct un-cooperativeness	1	2	1	2
Excessive dependency/demands	1	2	1	2
Suicide threats	1	2	1	2
Early termination Threats	1	2	1	2
Distorted view of therapist	1	2	1	2
Impersonal Presentation	1	2	1	2
Other	1	2	1	2

OVERALL THERAPIST RATING FORM

	yes	no	rec	Excellent						Poor
Therapist's skill at helping patient with intimate self disclosure	1	2	3	1	2	3	4	5	6	7
Therapist's ability to tend to the therapeutic relationship	1	2	3	1	2	3	4	5	6	7
Therapist's ability to focus session on appropriate topic	1	2	3	1	2	3	4	5	6	7
Therapist's ability to maintain appropriate therapeutic stance	1	2	3	1	2	3	4	5	6	7
Overall quality of the session	1	2	3	1	2	3	4	5	6	7
Patient's receptivity in this session	1	2	3	1	2	3	4	5	6	7

IPT-B TREATMENT MANUAL

ROLE TRANSITIONS PROTOCOL

SEPTEMBER 2001-August 2002

THE STRUCTURE OF IPT-B

IPT-B is based on the premise that symptoms of depression (IPC = psychological distress) regardless of biological vulnerability or personality, occur in a psychosocial and interpersonal context and is defined as occurring in 3 phases: Assessment; Middle; Termination
The structure for IPT-B has been directly derived from IPT for Depression (Klerman et al 1984)

OUTLINE SESSION 1: INITIATING IPT-B

Dealing with the Depression
Review of depressive symptoms using DSM-IV criteria
Give the syndrome a name
Explain depression and the treatment
Sick role given with positive emphasis on recovery

Relate Depression to Interpersonal Context
Review current and past interpersonal relationships as they relate to current depressive symptoms.
Review will be carried out as a homework task by patient to include the following:

- nature of interaction with significant persons
- expectations of patient and significant persons from each other and whether these have been fulfilled
- satisfying and unsatisfying aspects of the relationships
- changes the patient wants in the relationship

OUTLINE SESSION 2

Identification of Major Problem Area
Determine the problem area related to current depression and set treatment goals
Review of Interpersonal Inventory
Determine which relationship or aspect of a relationship is related to the depression and what might change it.

Explain the IPT-B Concepts and Contract
Outline your understanding of the problem.
Agree on treatment goals (which problem area will be the focus).
Describe procedures of IPT-B: "here and now" focus, need for patient to discuss important concerns; review of current interpersonal relations (to be carried out by patient at home),
Discussion of practical aspects of treatment
Length: 1 hour sessions (10 minutes at beginning to complete BDI-II).
Frequency: once a week for 8 weeks.
Times:
Policy for missed appointments: every week will be counted as a session so that the therapy must be completed within 8 weeks.

OUTLINE SESSIONS 3-6 The Problem Area (Focus)

Grief
Interpersonal Disputes
Role Transitions
Interpersonal Deficits
Each Problem area has a set of goals and strategies as outlined by Klerman et al (1984).

OUTLINE SESSIONS 7-8 Termination of Treatment

Explicit discussion of termination
Acknowledgement that termination is a time of grieving
Moves toward patient recognition of independent competence

DETAILED MANUAL SESSION 1

The first session is used to establish rapport with the patient. During this session, the following should be included (therapist 'checklist & rating' forms should act as a checklist at the end of every session):

Before patient is seen, ask to complete BDI-II

What has caused the need for treatment? *What has been going on in the patient's life that has caused the need for treatment and WHO was around (interpersonal context)*
Recent history of depressive condition including a review of past episodes and of particular interpersonal precipitants and/or consequences of the depression and ways in which previous depressive episodes have been resolved.
Review of depressive symptoms using the Hamilton Rating Scale as a basis
Depression diagnosis given using DSM-IV criteria
Suicidal intent must be carefully assessed using BPS guidelines
Education re depressive condition i.e. *depression is common with approximately 3-4% of the adult population at any one time in UK being diagnosable. Depression does respond to treatment and therefore the outlook is excellent.*
Sick Role given:
Which demanding activities can the patient cut back on?
Which pleasurable activities can the patient increase?
Who can help out?
If patient had a broken leg, who would help?
What would they do to help?
What things did patient used to enjoy which they have done less of recently?
Timetable daily activities to take into account typical symptom pattern
Relate depression to interpersonal context through a review of current and past interpersonal relationships as they relate to current depressive symptoms using **Interpersonal Inventory** as a basis for patient to carry out at home.
Something small and manageable i.e task agreed upon to gain sense of achievement
Initial discussion of practical aspects of treatment - 8 sessions for an hour a week - these should be booked in advance if at all possible.
At the end of the session, ask patient to complete the following questionnaires
Other contact questionnaire
Patient rating scale

***Complete Therapist checklist and Rating Scale*

DIAGNOSTIC CRITERIA FROM DSM-IV (APA, 1994)

Major Depressive Episode

depressed mood most of the day, nearly every day, as indicated by either subjective report (e.g. feels sad or empty) or observation made by others (e.g. appears tearful)

markedly diminished interest or pleasure in all, or almost all, activities most of the day, nearly every day (as indicated by either subjective account or observation made by others)

significant weight loss when not dieting or weight gain (e.g. a change of more than 5% of body weight in a month), or decrease or increase in appetite nearly every day.

insomnia or hypersomnia nearly every day

psychomotor agitation or retardation nearly every day (observable by others, not merely subjective feelings of restlessness or being slowed down)

fatigue or loss of energy nearly every day

feelings of worthlessness or excessive or inappropriate guilt (which may be delusional) nearly every day (not merely self-reproach or guilt about being sick)

diminished ability to think or concentrate, or indecisiveness, nearly every day (either by subjective account or as observed by others)

recurrent thoughts of death (not just fear of dying), recurrent suicidal ideation without a specific plan, or a suicide attempt or a specific plan for committing suicide

INTERPERSONAL INVENTORY FOR

Who have you been in contact with today? Last week?

FOR EACH PERSON:

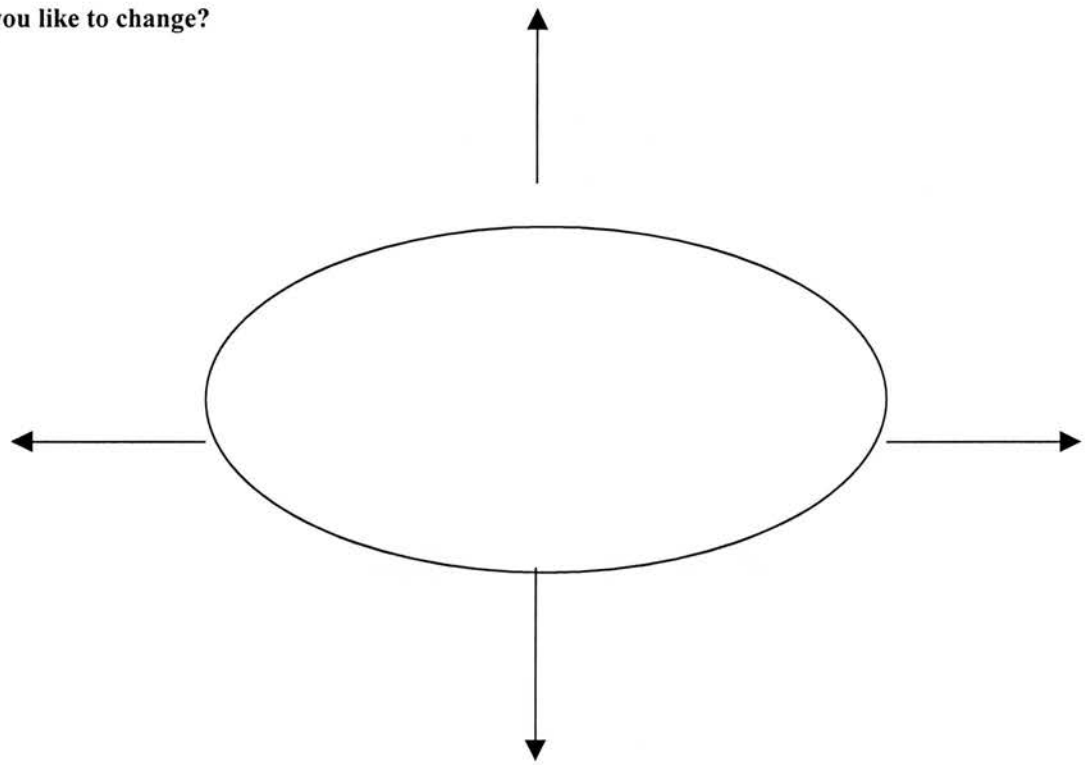
frequency of contact

activities shared

expectations

sat/unsat aspects

ways you like to change?



SESSION 2

Before patient is seen, ask to complete BDI-II

Symptoms of depression over past week reviewed using DSM-IV criteria - interpersonally (how have symptoms of depression influenced relationships?)

Expectations of therapy discussed

Explanation of IPT/basic assumptions - *relationships are central to the experience, from our experience of doing this with others, IPT works. Reassurance re: positive aspects.*

Review of Interpersonal Inventory

Determine which relationship or aspect of a relationship is related to the depression and what might change it

Discuss major problem area related to current depression (*this is in preparation to determine IPT formulation and identify potential focus for therapy with the patient).*

Discuss therapist and patient tasks working towards goals (*therapist task is to keep patient focused with regards to 'focus agreed' and patient task is to bring to therapy areas they wish to discuss pertinent to their depressive symptoms, particularly things that affect them emotionally)*

Review of practical aspects of treatment i.e. length, times, frequency & policy for missed appointments.

At the end of the session, ask patient to complete the following questionnaires

'Other contact' questionnaire

'Patient rating scale'

***Complete therapist checklist and rating scale*

SESSION 3

Before patient is seen, ask to complete BDI-II

Symptoms of depression over past week reviewed using DSM-IV criteria - interpersonally (how have symptoms of depression influenced relationships?)

Problem area identified with patient from last week - introducing the focus:

SESSION 3 - INTRODUCING ROLE TRANSITIONS

Do you remember that at the beginning I said that although the causes of depression are unknown, it is frequently associated with problems in interpersonal relationships. Problems in relating to others may bring on depression in some people whilst for others the symptoms of depression prevent them from dealing as successfully as they usually do. In this treatment, we will try to discover what you want and need from others and help you learn how to get it. You have mentioned previously that you do have problems and I think that will be ways in which we can help you to learn how to deal with more effectively.

Over the last 2 sessions, it seems to me that you have described a clear onset of your depression around about ***the time that*** *but you also have described that you were feeling this way before and that perhaps the transition from .....is more important. You have told me about episodes in your life that have been very difficult for you including .....*
In IPT, we try to get you back to feeling how you were before the onset of your depression and therefore it is very important that we spell out exactly what we are going to try to do here.

We will be discussing your life as it is right now, and reviewing your relationships with important people in your life. We will also be looking at what it was like for you in the old role and what your feelings are about what has been lost and what your feelings are about what has been gained.

I'd like to discuss with you the areas you describe as related to your depression.

One is the kind of transition you've made from

The second issue is how your feelings of depression may have been emphasised

If we are agreed, I'd like to tell you how we will proceed. Your task will be to talk about things that concern you, particularly things that affect you emotionally. We will be concentrating on the issues I described above but there may be other issues which are important, please feel free to raise them - I will be interested not only in what happened but also your feelings about these events. It is your responsibility to select topics which are most important to you.

STRATEGIES: (Not all strategies to be attempted at each session - only those that are appropriate)

- ***Review depressive symptoms***
- ***Relate depressive symptoms to difficulty in coping with recent life change***
- ***Review positive and negative aspects of old and new roles***
- ***Explore feeling about what is lost***
- ***Explore feelings about the change itself***
- ***Explore opportunities in new role***
- ***Realistically evaluate what is lost Encourage appropriate release of affect***
- ***Encourage development of social support system and of new skills called for in new role***

Treatment goals set: reiterate goals of IPT-B plus feedback of formulation/ identification of focus area: aim for pre-morbid functioning; what has been lost? For each problem area, what is the best

possible outcome, the most expectable outcome and the worst outcome? Who do you want a more intimate relationship with? One goal agreed on was to try to work out what has been happening with relationships and why you have found it difficult to be close to people and to try to help you find and establish more satisfying relationships.

What do you need to be doing to make those friends?

What are the areas that you are doing it all alone?

Questions for homework & ask patient to write a summary of their understanding of their depressive symptoms (see homework sheet for session 3)

At the end of the session, ask patient to complete the following questionnaires *Other contact questionnaire*

Patient rating scale

***Complete Therapist checklist and Rating Scale*

TASK FOR END OF SESSION 3

What does the change in role mean to you?
When you ....., how did your life change?
What important people were left behind?
How did you feel in this new role?
Tell me about what it was like in the old role?
What were the good things?
What were the bad things?
What did you like?
What did you not like?
How did it feel to give that up?
Tell me about the details of ..... - how did you feel in the new situation?
What was it like at first?
What is required of you now?
How hard is it?
What is going well?
What is going badly?
Feelings about the change - guilt....

If possible, try to write a summary of your understanding of what was happening in your life around about when you became depressed - who was around and how you were feeling - really try to define your feelings here.

SESSION 4

Before patient is seen, ask to complete BDI-II

Use the following strategies for sessions 3-6 (not all at every session):

STRATEGIES:

- ***Review depressive symptoms using DSM-IV criteria***
- ***Relate depressive symptoms to difficulty in coping with recent life change***
- ***Review positive and negative aspects of old and new roles***
- ***Explore feeling about what is lost***
- ***Explore feelings about the change itself***
- ***Explore opportunities in new role***
- ***Realistically evaluate what is lost Encourage appropriate release of affect***
- ***Encourage development of social support system and of new skills called for in new role***

At the end of the session, ask patient to complete the following questionnaires

*Other contact questionnaire; Patient rating scale **Complete Therapist checklist and Rating Scale*

SESSIONS 5 & 6

Before patient is seen, ask to complete BDI-II

STRATEGIES: (Not all strategies to be attempted at each session - only those that are appropriate)

- ***Review depressive symptoms***
- ***Relate depressive symptoms to difficulty in coping with recent life change***
- ***Review positive and negative aspects of old and new roles***
- ***Explore feeling about what is lost***
- ***Explore feelings about the change itself***
- ***Explore opportunities in new role***
- ***Realistically evaluate what is lost Encourage appropriate release of affect***
- ***Encourage development of social support system and of new skills called for in new role***

At the end of the session, ask patient to complete the following questionnaires

Other contact questionnaire

Patient rating scale

***Complete Therapist checklist and Rating Scale*

SESSION 7

Before patient is seen, ask to complete BDI-II

Review of depressive symptoms using DSM-IV criteria over past week

Explicit discussion of the end of treatment - *possible return of symptoms - normal - anxiety raised? Make the distinction between loss and relapse - we have the opportunity to model a successful ending and discussing feelings with regards to that.*

Explicit discussion of 8-12 months post therapy, there is the opportunity to see changes in the interpersonal world of the patient - this gives the chance to experience success.

Help patient move toward a recognition of his/her independent competence.

Review of course of treatment and progress with the patient

Patient given the opportunity to evaluate future needs

At the end of the session, ask patient to complete the following questionnaires *Other contact questionnaire, Patient rating scale **Complete Therapist checklist and Rating ScalE*

SESSION 8 - FINAL SESSION

Before patient is seen, ask to complete BDI-II

Review of depressive symptoms using DSM-IV criteria

Assess with patient early warning signals, and discuss procedures for re-entry into treatment if necessary

At the end of the session, ask patient to complete the following questionnaires: *Quality of Life Questionnaire - WHO Brief version; Significant others scale; HAM-D-R; SCID;*

Other contact questionnaire

Patient rating scale

***Complete Therapist checklist and Rating Scale*

IPT-B TREATMENT MANUAL

GRIEF PROTOCOL

SEPTEMBER 2001-August 2002

DETAILED MANUAL SESSION 1

The first session is used to establish rapport with the patient. During this session, the following should be included (therapist 'checklist & rating' forms should act as a checklist at the end of every session):

Before patient is seen, ask to complete BDI-II

1. What has caused the need for treatment? *What has been going on in the patient's life that has caused the need for treatment and WHO was around (interpersonal context)*
2. Recent history of depressive condition including a review of past episodes and of particular interpersonal precipitants and/or consequences of the depression and ways in which previous depressive episodes have been resolved.
3. Review of depressive symptoms using the Hamilton Rating Scale as a basis
4. Depression diagnosis given using DSM-IV criteria
5. Suicidal intent must be carefully assessed using BPS guidelines
6. Education re depressive condition i.e. *depression is common with approximately 3-4% of the adult population at any one time in UK being diagnosable. Depression does respond to treatment and therefore the outlook is excellent.*
7. Sick Role given:
   Which demanding activities can the patient cut back on?
   Which pleasurable activities can the patient increase?
   Who can help out?
   If patient had a broken leg, who would help?
   What would they do to help?
   What things did patient used to enjoy which they have done less of recently?
   Timetable daily activities to take into account typical symptom pattern
7. Relate depression to interpersonal context through a review of current and past interpersonal relationships as they relate to current depressive symptoms using **Interpersonal Inventory** as a basis for patient to carry out at home.
8. Something small and manageable i.e task agreed upon to gain sense of achievement
9. Initial discussion of practical aspects of treatment - 8 sessions for an hour a week - these should be booked in advance if at all possible.
10. At the end of the session, ask patient to complete the following questionnaires

Other contact questionnaire
Patient rating scale

***Complete Therapist checklist and Rating Scale*

SESSION 2

Before patient is seen, ask to complete BDI-II

1. Symptoms of depression over past week reviewed using DSM-IV criteria - interpersonally (how have symptoms of depression influenced relationships?)
2. Expectations of therapy discussed
3. Explanation of IPT/basic assumptions - *relationships are central to the experience, from our experience of doing this with others, IPT works. Reassurance re: positive aspects.*
4. Review of Interpersonal Inventory **Highly important to obtain a history of significant relationships with those who are now dead or otherwise absent. This should include the circumstances of the death and the patient's behavioural and emotional reaction to it.**
5. Determine which relationship or aspect of a relationship is related to the depression and what might change it
6. Discuss major problem area related to current depression (*this is in preparation to determine IPT formulation and identify potential focus for therapy with the patient).*

To diagnose abnormal grief: ***I notice that you don't mention your mother when discussing your parents. Has anyone you've been close to died recently? Could you tell me about the death? When? Where? What circumstances? How did it feel when you learned of the death? How were you the next few weeks? Did you carry on as usual?***

7. Discuss therapist and patient tasks working towards goals (*therapist task is to keep patient focused with regards to 'focus agreed' and patient task is to bring to therapy areas they wish to discuss pertinent to their depressive symptoms, particularly things that affect them emotionally)*
8. Review of practical aspects of treatment i.e. length, times, frequency & policy for missed appointments.
9. At the end of the session, ask patient to complete the following questionnaires

'Other contact' questionnaire

'Patient rating scale'

***Complete therapist checklist and rating scale*

SESSION 3

Before patient is seen, ask to complete BDI-II

1. Symptoms of depression over past week reviewed using DSM-IV criteria - interpersonally (how have symptoms of depression influenced relationships?)
2. Problem area identified with patient from last week - introducing the focus:

SESSION 3 - INTRODUCING GRIEF FOCUS

Do you remember that at the beginning I said that although the causes of depression are unknown, it is frequently associated with problems in interpersonal relationships. Problems in relating to others may bring on depression in some people whilst for others the symptoms of depression prevent them from dealing as successfully as they usually do. In this treatment, we will try to discover what you want and need from others and help you learn how to get it. You have mentioned previously that you do have problems and I think that will be ways in which we can help you to learn how to deal with more effectively.

Over the last 2 sessions, it seems to me that you have described a clear onset of your depression around .....but you also have described that you were feeling this way before and that perhaps the loss of .....is more important. You have told me about episodes in your life that have been very difficult for you including

In IPT, we try to get you back to feeling how you were before the onset of your depression and therefore it is very important that we spell out exactly what we are going to try to do here.

We will be discussing your life as it is right now, and reviewing your relationships with important people in your life.

I'd like to discuss with you the areas you describe as related to your depression.

If we are agreed, I'd like to tell you how we will proceed. Your task will be to talk about things that concern you, particularly things that affect you emotionally. We will be concentrating on the issues I described above but there may be other issues which are important, please feel free to raise them I will be interested not only in what happened but also your feelings about these events. It is your responsibility to select topics which are most important to you.

STRATEGIES: (Not all strategies to be attempted at each session - only those that are appropriate)

- ***Review depressive symptoms***
- ***Relate depressive symptoms to death of significant other***
- ***Reconstruct the patient's relationship with the deceased***
- ***Describe the sequence and consequences of events just prior to, during, and after the death.***
- ***Explore associated feelings (negative as well as positive)***
- ***Consider possible ways of becoming involved with others.***

3. Treatment goals set: reiterate goals of IPT-B plus feedback of formulation/ identification of focus area: aim for pre-morbid functioning. For each problem area, what is the best possible outcome, the most expectable outcome and the worst outcome? Who do you want a more intimate relationship with? One goal agreed on was to try to work out what has been happening with

relationships and why you have found it difficult to be close to people and to try to help you find and establish more satisfying relationships.

What do you need to be doing to make those friends?

What are the areas that you are doing it all alone?

4. Questions for homework & ask patient to write a summary of their understanding of their depressive symptoms (see homework sheet for session 3)

5. At the end of the session, ask patient to complete the following questionnaires *Other contact questionnaire*

Patient rating scale

***Complete Therapist checklist and Rating Scale*

TASK FOR END OF SESSION 3

1. What does the loss mean to you?
2. When you lost……., how did your life change?
3. What were the ups and downs of you relationship with…… How did you feel in this new role?
4. What were the good things?
5. What were the bad things?
6. What did you like?
7. What did you not like?
8. What is your life like now?
9. How have you tried to make up for the loss?
10. Who are your friends?
11. What activities might be enjoyable?
12. Tell me about the details of …….. - how did you feel in the new situation?
13. What was it like at first?
14. What is required of you now?
15. How hard is it?
16. What is going well?
17. What is going badly?
18. Feelings about the loss - guilt….

If possible, try to write a summary of your understanding of what was happening in your life around about when you became depressed – who was around and how you were feeling - *really* try to define your feelings here.

SESSION 4

Before patient is seen, ask to complete BDI-II

1. Use the following strategies for sessions 3-6 (not all at every session):

STRATEGIES: (Not all strategies to be attempted at each session - only those that are appropriate)

- ***Review depressive symptoms***
- ***Relate depressive symptoms to death of significant other***
- ***Reconstruct the patient's relationship with the deceased***
- ***Describe the sequence and consequences of events just prior to, during, and after the death.***
- ***Explore associated feelings (negative as well as positive)***
- ***Consider possible ways of becoming involved with others.***

2. At the end of the session, ask patient to complete the following questionnaires

Other contact questionnaire

Patient rating scale

***Complete Therapist checklist and Rating Scale*

SESSIONS 5 & 6

Before patient is seen, ask to complete BDI-II

STRATEGIES: (Not all strategies to be attempted at each session - only those that are appropriate)

- ***Review depressive symptoms***
- ***Relate depressive symptoms to death of significant other***
- ***Reconstruct the patient's relationship with the deceased***
- ***Describe the sequence and consequences of events just prior to, during, and after the death.***
- ***Explore associated feelings (negative as well as positive)***
- ***Consider possible ways of becoming involved with others.***

2. At the end of the session, ask patient to complete the following questionnaires *Other contact questionnaire*

Patient rating scale

***Complete Therapist checklist and Rating Scale*

SESSION 7

Before patient is seen, ask to complete BDI-II

1. Review of depressive symptoms using DSM-IV criteria over past week
2. Explicit discussion of the end of treatment - *possible return of symptoms - normal - anxiety raised? Make the distinction between loss and relapse - we have the opportunity to model a successful ending and discussing feelings with regards to that.*
3. Explicit discussion of 8-12 months post therapy, there is the opportunity to see changes in the interpersonal world of the patient - this gives the chance to experience success.
4. Help patient move toward a recognition of his/her independent competence.
5. Review of course of treatment and progress with the patient
6. Patient given the opportunity to evaluate future needs
7. At the end of the session, ask patient to complete the following questionnaires *Other contact questionnaire; Patient rating scale **Complete Therapist checklist and Rating Scale*

SESSION 8 - FINAL SESSION

Before patient is seen, ask to complete BDI-II

1. Review of depressive symptoms using DSM-IV criteria
2. Assess with patient early warning signals, and discuss procedures for re-entry into treatment if necessary
3. At the end of the session, ask patient to complete the following questionnaires

Quality of Life Questionnaire - WHO Brief version

Significant others scale

HAM-D-R

Attachment scales

SCID

Other contact questionnaire

Patient rating scale

***Complete Therapist checklist and Rating Scale*

IPT-B TREATMENT MANUAL

INTERPERSONAL DISPUTES PROTOCOL

SEPTEMBER 2001-August 2002

DETAILED MANUAL SESSION 1

The first session is used to establish rapport with the patient. During this session, the following should be included (therapist 'checklist & rating' forms should act as a checklist at the end of every session):

Before patient is seen, ask to complete BDI-II

What has caused the need for treatment? *What has been going on in the patient's life that has caused the need for treatment and WHO was around (interpersonal context)*
Recent history of depressive condition including a review of past episodes and of particular interpersonal precipitants and/or consequences of the depression and ways in which previous depressive episodes have been resolved.
Review of depressive symptoms using the Hamilton Rating Scale as a basis
Depression diagnosis given using DSM-IV criteria
Suicidal intent must be carefully assessed using BPS guidelines
Education re depressive condition i.e. *depression is common with approximately 3-4% of the adult population at any one time in UK being diagnosable. Depression does respond to treatment and therefore the outlook is excellent.*
Sick Role given:

Which demanding activities can the patient cut back on?
Which pleasurable activities can the patient increase?
Who can help out?
If patient had a broken leg, who would help?
What would they do to help?
What things did patient used to enjoy which they have done less of recently?
Timetable daily activities to take into account typical symptom pattern

Relate depression to interpersonal context through a review of current and past interpersonal relationships as they relate to current depressive symptoms using **Interpersonal Inventory** as a basis for patient to carry out at home.
Something small and manageable i.e task agreed upon to gain sense of achievement
Initial discussion of practical aspects of treatment - 8 sessions for an hour a week - these should be booked in advance if at all possible.
At the end of the session, ask patient to complete the following questionnaires
Other contact questionnaire
Patient rating scale

***Complete Therapist checklist and Rating Scale*

SESSION 2

Before patient is seen, ask to complete BDI-II

Symptoms of depression over past week reviewed using DSM-IV criteria - interpersonally (how have symptoms of depression influenced relationships?)

Expectations of therapy discussed

Explanation of IPT/basic assumptions - *relationships are central to the experience, from our experience of doing this with others, IPT works. Reassurance re: positive aspects.*

Review of Interpersonal Inventory

Determine which relationship or aspect of a relationship is related to the depression and what might change it

Discuss major problem area related to current depression (*this is in preparation to determine IPT formulation and identify potential focus for therapy with the patient). Patient must give evidence of overt or covert conflicts with a significant other*

(Goals: if dispute, identify dispute, choose plan of action, modify expectations or faulty communication to bring about a satisfactory resolution)

Discuss therapist and patient tasks working towards goals (*therapist task is to keep patient focused with regards to 'focus agreed' and patient task is to bring to therapy areas they wish to discuss pertinent to their depressive symptoms, particularly things that affect them emotionally)*

Review of practical aspects of treatment i.e. length, times, frequency & policy for missed appointments.

At the end of the session, ask patient to complete the following questionnaires

'Other contact' questionnaire

'Patient rating scale'

***Complete therapist checklist and rating scale*

SESSION 3

Before patient is seen, ask to complete BDI-II

Symptoms of depression over past week reviewed using DSM-IV criteria - interpersonally (how have symptoms of depression influenced relationships?)

Problem area identified with patient from last week - introducing the focus:

SESSION 3 - INTRODUCING DISPUTES FOCUS

Do you remember that at the beginning I said that although the causes of depression are unknown, it is frequently associated with problems in interpersonal relationships. Problems in relating to others may bring on depression in some people whilst for others the symptoms of depression prevent them from dealing as successfully as they usually do. In this treatment, we will try to discover what you want and need from others and help you learn how to get it. You have mentioned previously that you do have problems and I think that will be ways in which we can help you to learn how to deal with more effectively.

Over the last 2 sessions, it seems to me that you have described a clear onset of your depression around .....but you also have described that you were feeling this way before and that perhaps the .....is more important. You have told me about episodes in your life that have been very difficult for you including

In IPT, we try to get you back to feeling how you were before the onset of your depression and therefore it is very important that we spell out exactly what we are going to try to do here.

We will be discussing your life as it is right now, and reviewing your relationships with important people in your life.

I'd like to discuss with you the areas you describe as related to your depression.

If we are agreed, I'd like to tell you how we will proceed. Your task will be to talk about things that concern you, particularly things that affect you emotionally. We will be concentrating on the issues I described above but there may be other issues which are important, please feel free to raise them · I will be interested not only in what happened but also your feelings about these events. It is your responsibility to select topics which are most important to you.

STRATEGIES: (Not all strategies to be attempted at each session - only those that are appropriate)

- ***Review depressive symptoms***
- ***Relate depressive symptoms' onset to overt or covert dispute with significant other and with whom patient is currently involved.***
- ***Determine stage of dispute:***

d. ***Renegotiation (calm down participants to facilitate resolution)***
e. ***Impasse (increase disharmony in order to reopen negotiation)***
f. ***Dissolution (assist mourning)***

- ***Understand how nonreciprocal role expectations relate to dispute:***

a. ***What are the issues in the dispute?***
b. ***What are the differences in expectations and values?***
c. ***What are the options?***
d. ***What is the likelihood of finding alternatives?***
e. ***What resources are available to bring about change in the relationship?***

- ***Are there parallels in other relationships?***

a. ***What is the patient gaining?***
b. ***What unspoken assumptions lie behind the patient's behaviour?***

- ***How is the dispute perpetuated?***

Treatment goals set: reiterate goals of IPT-B plus feedback of formulation/ identification of focus area: aim for pre-morbid functioning. For each problem area, what is the best possible outcome, the most expectable outcome and the worst outcome? Who do you want a more intimate relationship with? One goal agreed on was to try to work out what has been happening with relationships and why you have found it difficult to be close to people and to try to help you find and establish more satisfying relationships.

What do you need to be doing to make those friends?

What are the areas that you are doing it all alone?

Questions for homework & ask patient to write a summary of their understanding of their depressive symptoms (see homework sheet for session 3)

At the end of the session, ask patient to complete the following questionnaires *Other contact questionnaire; Patient rating scale **Complete Therapist checklist and Rating Scale*

TASK FOR END OF SESSION 3

1. What does the dispute mean to you?
2. What do you want/expect from this relationship?
3. What does the significant other wants/expect from this relationship?
4. What are the options?
5. What is the likelihood of finding alternatives?
6. What resources are available to bring about change in the relationship?
7. What were the ups and downs of you relationship with..... What were the good things?
8. What were the bad things?
9. What did you like?
10. What did you not like?
11. What is your life like now?
12. Who are your friends?
13. Tell me about the details of .....
14. What was it like at first?
15. What is required of you now?
16. How hard is it?
17. What is going well?
18. What is going badly?
19. Feelings about the dispute - guilt....

If possible, try to write a summary of your understanding of what was happening in your life around about when you became depressed - who was around and how you were feeling - *really* try to define your feelings here.

SESSION 4

Before patient is seen, ask to complete BDI-II

Use the following strategies for sessions 3-6 (not all at every session):

STRATEGIES: (Not all strategies to be attempted at each session - only those that are appropriate)

- ■ *Review depressive symptoms*
- ■ *Relate depressive symptoms' onset to overt or covert dispute with significant other and with whom patient is currently involved.*
- ■ *Determine stage of dispute:*

g. Renegotiation (calm down participants to facilitate resolution)
h. Impasse (increase disharmony in order to reopen negotiation)
i. Dissolution (assist mourning)

- ■ *Understand how nonreciprocal role expectations relate to dispute:*

f. What are the issues in the dispute?
g. What are the differences in expectations and values?
h. What are the options?
i. What is the likelihood of finding alternatives?
j. What resources are available to bring about change in the relationship?

- ■ *Are there parallels in other relationships?*

c. What is the patient gaining?
d. What unspoken assumptions lie behind the patient's behaviour?

- ■ *How is the dispute perpetuated?*

At the end of the session, ask patient to complete the following questionnaires

Other contact questionnaire; Patient rating scale; ***Complete Therapist checklist and Rating Scale*

SESSIONS 5 & 6

Before patient is seen, ask to complete BDI-II

STRATEGIES: (Not all strategies to be attempted at each session - only those that are appropriate)

- ■ *Review depressive symptoms*
- ■ *Relate depressive symptoms' onset to overt or covert dispute with significant other and with whom patient is currently involved.*
- ■ *Determine stage of dispute:*

j. Renegotiation (calm down participants to facilitate resolution)
k. Impasse (increase disharmony in order to reopen negotiation)
l. Dissolution (assist mourning)

- ■ *Understand how nonreciprocal role expectations relate to dispute:*

k. What are the issues in the dispute?
l. What are the differences in expectations and values?
m. What are the options?
n. What is the likelihood of finding alternatives?
o. What resources are available to bring about change in the relationship?

- ■ *Are there parallels in other relationships?*

e. What is the patient gaining?
f. What unspoken assumptions lie behind the patient's behaviour?

- ■ *How is the dispute perpetuated?*

At the end of the session, ask patient to complete the following questionnaires *Other contact questionnaire; Patient rating scale **Complete Therapist checklist and Rating Scale*

SESSION 7

Before patient is seen, ask to complete BDI-II

Review of depressive symptoms using DSM-IV criteria over past week

Explicit discussion of the end of treatment - *possible return of symptoms - normal - anxiety raised? Make the distinction between loss and relapse - we have the opportunity to model a successful ending and discussing feelings with regards to that.*

Explicit discussion of 8-12 months post therapy, there is the opportunity to see changes in the interpersonal world of the patient - this gives the chance to experience success.

Help patient move toward a recognition of his/her independent competence.

Review of course of treatment and progress with the patient

Patient given the opportunity to evaluate future needs

At the end of the session, ask patient to complete the following questionnaires *Other contact questionnaire; Patient rating scale **Complete Therapist checklist and Rating Scale*

SESSION 8 - FINAL SESSION

Before patient is seen, ask to complete BDI-II

Review of depressive symptoms using DSM-IV criteria

Assess with patient early warning signals, and discuss procedures for re-entry into treatment if necessary

At the end of the session, ask patient to complete the following questionnaires

Quality of Life Questionnaire - WHO Brief version

Significant others scale

HAM-D-R

Attachment scales

SCID

Other contact questionnaire

Patient rating scale

***Complete Therapist checklist and Rating Scale*

RELIABLE CHANGE INDEX USING POPULATION IN THE TEST DATA

Reliable Change Index (RCI) = $(x_1 - x_2) / (\text{SEDIFF})$

	RHRSD END (of Treatment) RCI SED= $\sqrt{2(SE_M)^2}$ = 4.13 Observer	RHRSD 2 Month Follow-up RCI SED= $\sqrt{2(SE_M)^2}$ = 4.13 Observer	RHRSD END (of Treatment) RCI SED= $\sqrt{2(SE_M)^2}$ = 4.70 Self Report	RHRSD 2 Month Follow-up RCI SED= $\sqrt{2(SE_M)^2}$ = 4.70 Self Report	BDI-II END (of Treatment) RC SED= $\sqrt{2(SE_M)^2}$ = 4.36 Self Report	BDI-II 2 Month Follow-up RCI SED= $\sqrt{2(SE_M)^2}$ = 4.36 Self Report
1	2.17*	2.18*	2.77*	2.76*	6.65*	6.65*
2	1.45	-1.45	-1.49	-1.49	1.15	1.15
3	1.21	1.21	-0.64	-0.64	1.83	1.83
4	2.66*	2.66*	2.13*	2.13*	4.59*	4.59*
5	0	-2.66	-0.43	0.85	-0.23	-0.23
6	3.63*	3.63*	1.06	1.06	0.69	0.69
7	0	-0.48	-0.85	0.85	0	0
8	4.6*	4.6*	2.76*	2.76*	5.05*	5.05*
9	0	0	0.21	-0.85	1.15	0.46
10	0	0	-2.13	-2.73	2.29*	2.29*
11	***0***	***0***	***0***	***0***	***0***	***0***
12	0	0.73	0	0	0.23	0.69
13	***0***	***0***	***0***	***0***	***0***	***0***
14	-0.48	-0.48	0	0	0.92	0.92
15	0.48	3.63*	0.42	4.25*	5.5*	9.86*
16	0.24	0.48	0.85	1.49	-0.46	0.92
17	2.18*	2.13*	1.7	1.7	2.29*	2.29*
18	0	0.24	1.7	2.98*	2.29*	1.38
19	0.24	0.73	0.64	0.64	1.38	-0.46
20	***0***	***0***	***0***	***0***	***0***	***0***
21	-0.24	0	1.06	0.85	3.44*	1.38
22	0	0	0.21	0.21	0	0
23	0.24	0.24	3.19*	3.19*	2.98*	2.98*
24	***0***	***0***	***0***	***0***	***6.42****	***6.42****
25	3.87*	4.6*	1.91	5.32*	2.75*	0.69
26	2.18*	2.18*	1.49	1.49	0.92	0.92
27	1.21	1.94	-1.7	-0.85	1.15	1.15
28	1.21	1.21	2.98*	3.62*	6.19*	6.88*
29	1.69	1.69	0.42	0.42	1.38	1.38
30	0.73	0.73	1.06	1.49	2.06*	1.83
31	4.84*	5.33*	3.4*	3.4*	2.75*	4.36*
32	***0***	***0***	***0***	***0***	***0.23***	***0.23***
33	3.87*	4.84*	1.91	3.19*	5.73*	5.96*
34	1.94	0.24	1.06	-0.21	0.46	0.23
35	6.78*	6.78*	3.19*	3.19*	5.96*	5.96*
36	4.12*	4.36*	4.04*	4.25*	3.21*	4.82*
37	0.73	0.73	0.42	0.42	4.82*	4.82*
38	0.24	4.6*	2.98*	4.25*	2.52*	2.98*
39	3.34*	3.39*	2.98*	2.76*	1.61	2.29*
40	***0***	***0***	***0***	***0***	***2.75****	***2.75****
41	0	0	0	0	6.88*	6.88*
42	-0.24	-0.24	-1.06	-1.06	-5.05	-5.05
43	2.18	2.18*	2.13*	2.13*	1.38	1.15
44	0.24	-0.24	-0.21	-0.21	1.38	2.29*
45	3.63*	3.63*	3.19*	3.19*	4.82*	4.81*
46	0	3.39*	-0.64	3.83*	-0.23	4.81*
47	1.69	1.69	2.98*	2.98*	3.44*	3.44*
48	***0***	***0***	***0***	***0***	***2.06****	***2.06****
49	2.18*	2.18*	5.96*	6.8*	8.72*	8.94*

*>1.96 therefore improved status is not just due to inherent unreliability of test
1-23 = Waiting List Control Group
24-49 = IPT-B Intervention Group
Those highlighted refer to Intent to Treat Group

JACOBSON'S RELIABLE CHANGE INDEX

Reliable Change Index (RCI) = $(x_1 - x_2)$ / (SEDIFF)

Using comparisons with Fava et al, (1982) normative data - see Table 18.0

Standard error of measurement of a score (SEM) = $Sx\ \sqrt{(1 - r_{xx})}$

Sx = Standard deviation of the population in the test
r_{xx} = reliability of the test

Standard error of a difference score (SEDIFF) = $\sqrt{2(SE_M)_2}$

Reliable Change Index (RCI) = $(x_1 - x_2)$ / (SEDIFF)

χ_1 = pre-treatment score
χ_2 = post-treatment score
The critical value for the RCI to be statistically significant = 1.96

REVISED HAMILTON RATING FOR DEPRESSION : IK and LN
CLINICIAN VERSION

CLINICAL INTERVIEW at 3 follow up times (end of treatment; 2 and 4 month follow up)

Mean = 6.1 (SEM) = $Sx\ \sqrt{(1 - r_{xx})}$

Sx = 6.53 (SEM) = $6.53\sqrt{(1 - 0.8)} = 2.92$

$r_{xx'}$ = 0.8 (SEDIFF) = $\sqrt{2(SE_M)_2}$

(SEDIFF) = $\sqrt{2(2.92)_2} = 4.13$

	Pre treatment	End Treatment	RCI end	2 month follow up	RCI 2 mo	4 month follow up	RCI 4 mo
IK	19	3	3.87*	0	4.60*	2	4.12*
LN	25	21	0.97	23	0.48	22	0.73

* Exceeds 1.96 therefore improved status is not just due to inherent unreliability of test

REVISED HAMILTON RATING FOR DEPRESSION : IK & LN
SELF REPORT PROBLEM INVENTORY

Reliable Change Index (RCI) = $(x_1 - x_2)$ / (SEDIFF)

Mean = 16 (SEM) = $Sx\ \sqrt{(1 - r_{xx})}$

Sx = 7.4 (SEM) = $7.4\sqrt{(1 - 0.8)} = 3.31$

$r_{xx'}$ = 0.8 (SEDIFF) = $\sqrt{2(SE_M)_2}$

(SEDIFF) = $\sqrt{2(3.31)_2} = 4.70$

	Pre treatment	End Treatment	RCI end	2 month follow up	RCI 2 mo	4 month follow up	RCI 4 mo
IK	31	22	1.91	6	5.32*	6	5.32*
LN	28	26	0.42	27	0.21	27	0.21

*Exceeds 1.96 therefore improved status is not just due to inherent unreliability of test

BECK DEPRESSION INVENTORY II: IK

Reliable Change Index (RCI) = $(x_1 - x_2)$ / (SEDIFF)

Mean = 7.65 (SEM) = $Sx\sqrt{(1-r_{xx})}$

Sx = 11.64 (SEM) = $11.64\sqrt{(1-0.93)} = 3.08$

$r_{xx'}$ = 0.93 (SEDIFF) = $\sqrt{2(SE_M)_2}$

(SEDIFF) = $\sqrt{2(3.08)_2} = 4.36$

	Pre treatment	End Treatment	RCI end	2 month follow up	RCI 2 mo	4 month follow up	RCI 4 mo
IK	27	15	2.75*	4	5.28*	3	5.50*
LN	37	31	1.38	30	1.61	31	1.38

* Exceeds 1.96 therefore improved status is not just due to inherent unreliability of test

SUMMARY OF THE MAJOR STRENGTHS AND WEAKNESSES OF THE PRESENT STUDY

STRENGTHS	WEAKNESSES	STRENGTHS & WEAKNESSES The design of the study:	
		STRENGTH	*WEAKNESS*
Original adaptation carefully planned & executed with comparisons drawn between IPC and IPT.	Lack of comparison group for specificity	Only satisfactory method of assigning treatments in a clinical trial is by randomisation	Results are unlikely to generalise to clinical practice
IPT-B initial tested on a pilot case-study	Lack of stratification of atypical features of depression	Integrity and adherence to IPT-B rated	Potential limit of generalisability of the results.
Systematic bias avoided	Lack of compliance with patient diaries (to account for external bias)	Specific manuals ensure results are capable of replication AND it is considered meaningless to report any data concerning an adapted model of IPT, without stating exactly what such a treatment entailed	As therapists do not follow manuals in community results are not generalisable
Examination and interpretation of the effect size as a measure of improvement	Lack of blind ratings (detection bias)		
Economic evaluation conducted alongside study	Published data were used to *estimate* the relative cost effectiveness of CBT		
Examination the clinical significance of the findings			
Two sample populations: completer and intention-to-treat, stratified for severity of depression			